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Editorial

Vascular closure devices: the jury is still out

Dispositivos de cierre vascular: el debate sigue abierto

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Transcatheter aortic valve implantation (TAVI) is an established treatment for elderly patients with severe symptomatic aortic stenosis. Currently, most procedures are performed through transfemoral transcatheter aortic valve implantation (TF-TAVI) under conscious sedation via vascular access with safe and effective closure.[1] Nonetheless, large-bore transcatheter arterial accesses are inherently associated with a higher risk of vascular and hemorrhagic complications.[2]

The use of vascular closure devices (VCDs) in endovascular procedures has grown exponentially. Their emergence has reduced time to hemostasis, facilitated early ambulation and discharge, and reduced hospitalization costs.[2-4]

However, failed VCDs are not an uncommon finding (1%-8%), and vascular and hemorrhagic complications—most commonly found at the access site—can sometimes determine procedural success or failure.[5,6] Vascular complications significantly contribute to clinical outcomes in the short- and long-term, including length of stay, rehospitalizations, need for blood transfusions, and all-cause mortality.[2,4] Therefore, successful arterial access and closure is critical in TAVI.[2,7,8]

CURRENT DEVICES

The most widely used VCDs for large-bore arteriotomy closure are the suture-mediated closure system, Perclose ProGlide system (Abbott Vascular, United States), and the most recent plug-based MANTA vascular closure device (Teleflex/Essential Medical, United States).

The failure mechanisms associated with the Perclose ProGlide device include suture-related malfunction, unsuccessful deployment, and incomplete vessel wall apposition. Potential errors associated with the MANTA device include failed deployment, intraluminal or subcutaneous deployment, collagen detachment, delivery handle-related arterial occlusion, and incomplete handle apposition.[5,6,8]

The first feasibility studies ever conducted on the MANTA device showed promising safety and efficacy. Afterwards, several registries have presented their findings that compare favorably with suture techniques.[8-11]

Two recent randomized clinical trials have compared the 2 techniques. The MASH trial included 210 patients and found no differences in its primary endpoint: puncture site-related major and minor complications (10% with the MANTA vs 4% with the ProGlide; $P = .16$).[6] In contrast, in the CHOICE-CLOSURE trial of 516 patients, the MANTA device was associated with a higher rate of puncture site-related major and minor vascular complications (19.4% vs 12% with ProGlide; $P = .029$), and a similar incidence of puncture-site bleeding (11.6% vs 7.4%; $P = .133$).[12]

In an article published in *REC: Interventional Cardiology*, Martinho et al.[13] present an interesting single-center observational study on the largest real-world experience with the MANTA device. The aim of the study was to evaluate the safety and efficacy profile of the device in a consecutive unselected cohort of patients referred for TF-TAVI. The registry included 245 patients from March 2020 through February 2022. The participants' median age was 81 years, 52.7% were women, and the median EuroSCORE II was 3.15%. The 30-day TF-TAVI puncture site-related vascular complications were studied according to the Valve Academic Research Consortium (VARC) criteria. Regarding the primary outcome measure of the study—efficacy according to the VARC-3 criteria—successful puncture-site closure was achieved in 92.2% of participants. There were no major vascular or hemorrhagic complications, and only 8.6% experienced minor vascular complications according to the VARC-3 criteria (secondary safety outcome measure). The main predictors of device failure were a minimum femoral artery diameter and, consequently, a higher sheath-to-femoral artery diameter ratio, and the presence of more tortuous and calcified arterial accesses.[13]

Compared with the most recent clinical trials, the study by Martinho et al.[13] found rates of device failure that were lower than those in the MASH trial (7.8% vs 20%), but higher than those reported by the CHOICE-CLOSURE trial (4.7%). According to the authors, some of these differences may be attributed to the varying and inconsistent definitions of device failure across the studies.[6,12]

According to researchers, the study limitations include its single-center retrospective design, the absence of comparisons with other closure devices, and the lack of postoperative ultrasound scans for some of the participants (which were mandatory in the CHOICE-CLOSURE trial, potentially contributing to a higher detection rate of access site-related complications).[12] We should also

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mention that the registry included only patients considered eligible for closure with the MANTA device and excluded those with "unsuitable" anatomies.

To date, the available information, which includes numerous observational studies, 2 current randomized controlled trials, and more than 1 meta-analysis, suggests that vascular and hemorrhagic complications associated with collagen-based VCDs are quite similar to those of suture-based devices. No significant differences in the VCD failure rate have been reported, with identical 30-day all-cause mortality rates in the 2 groups.

CONCLUSIONS

The gradual reduction in the rate of vascular complications is the result of better preoperative assessment and technological support. Meticulous preoperative planning, with multidetector computed tomography for iliofemoral arterial axis study and ultrasound-guided access, should allow for an optimal approach to the access site and avoidance of incorrect cannulations.

Undoubtedly, cannulation of severely calcified arteries is associated with worse outcomes because of the difficulty involved in attaching the suture systems, and the higher risk of poor plug device apposition. Conversely, puncture sites without wall calcification should consistently yield better results, regardless of the type of VCD used.

Finally, regardless of the system used, angiographic or ultrasound confirmation after closure is always necessary to identify undetected VCD failures, vascular occlusions, or subcutaneous deployments, and expedite the implementation of corrective measures.[5,13]

In the search for the ideal VCD, several criteria have been proposed: successful deployment with immediate hemostasis in ≥ 98% of procedures, reduction of device-related major vascular complications to ≤ 1%, versatility to adapt to challenging anatomies, universal applicability with minimal exclusions, user-friendliness, easy access to the arterial site after closure, and the potential for early ambulation.[5] Such a perfect closure device, however, is still far from being a reality, which is why VCD innovation must continue to minimize vascular complications and achieve such goals.

A less well studied yet undoubtedly pivotal variable to achieve favorable outcomes with any VCD is the operator's experience, which is key to guaranteeing closure success and reducing VCD-related complications. However, measuring, quantifying, and analyzing this variable across different studies is a daunting task. Thus, although the perfect device may never become a reality, there will always be experienced operators who prefer certain types of VCDs.

With the current results, the decision to choose one VCD over another should be based on the patient's anatomy and basically on the operator's preferences and experience. An important consideration is that, to date, the MANTA device is more expensive than ProGlide, which, added to the substantially larger number of patients treated with TAVI, could pose a major obstacle to its selection in preference to suture-based systems.

In the meantime, we should consider innovations and technological advancements in the field of VCDs as welcome news for the interventional community. Soon, these advancements will likely position TF-TAVI as the technique of choice for most patients with symptomatic aortic stenosis.

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CONFLICTS OF INTEREST

None declared.

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Editorial

Transcatheter aortic valve replacement for noncalcified aortic regurgitation. Where are we now?

Implante de prótesis aórtica transcatéter en insuficiencia aórtica no calcificada. ¿En qué punto estamos?

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a well-established procedure for severe symptomatic aortic stenosis. Previously, this procedure was used exclusively to treat inoperable and high-risk patients but is now a common approach for intermediate and low-risk populations. In parallel, there has been growing global experience in several off-label scenarios, as in bicuspid, valve-in-valve, and noncalcified aortic regurgitation (NCAR).[1]

AORTIC REGURGITATION

Due to abnormalities in the aortic leaflets or their supporting structures (ie, aortic root and annulus), or both, aortic regurgitation (AR) causes diastolic reflux of blood from the aorta into the left ventricle (LV). This leads to LV volume overload and dilatation, allowing the ejection of a larger stroke volume. However, over time, it results in a decline in systolic function causing symptoms conferring a poor prognosis.[2] Current European and American guidelines recommend surgical intervention when significant AR is accompanied by symptoms, reduced LV ejection fraction, or severe LV dilatation.[3-4] Although moderate or severe AR affects around 2.2% of the population aged 70 years or older, up to 30% of these individuals are deemed inoperable due to advanced age or comorbidities, with percutaneous options—including dedicated and nondedicated devices—gaining increased interest due to the absence of safe surgical alternatives.[5]

CHALLENGES OF TAVI IN NCAR

Specific challenges for transcatheter devices are due to the characteristics of patients with NCAR, including larger aortic annular dimensions, aortic root dilatation, insufficient annular calcification for anchoring, and larger stroke volume with backflow to the LV causing a "suction effect". All of these factors create difficulties in selecting the appropriate device and positioning and deploying it correctly, and consequently increase the risk of embolization or malpositioning of the prosthesis, requiring a second valve implantation. Ultimately, these challenges are associated with increased mortality. In particular, the primary concern is valve embolization. To reduce the risk of this complication, prosthesis oversizing is routinely performed, but the exact degree of oversizing with each

device has not been standardized. Furthermore, oversizing is associated with a high rate of conduction system disturbances and may carry a higher risk of annular rupture.

DEVICES AND EVIDENCE

There are 2 dedicated-devices for NCAR: The Trilogy system (JenaValve Technology Inc, California, United States) and the J-Valve (JC Medical Inc, California, United States). The most recent experience with these dedicated devices has been reported by Adam et al.[6] and García et al.[7] The Trilogy system was associated with a 30-day mortality rate of 1.7% (vs 3.7% with J-Valve) and both had 0% ≥ moderate residual AR. However, 7.4% required conversion to surgery with the J-Valve, leading to some technical changes in the technology. Of note, the pacemaker rate with both systems was above 10% (19.6% and 13%, respectively). These promising dedicated technologies still have certain shortcomings, the main one being the lack of sizes covering large annuli; indeed, for 10% oversizing, the proportion of AR patients whose aortic structures were above the recommended indications was up to $\sim$50%.[8]

The first-in-human compassionate use of SAPIEN (Edwards Lifesciences, California, United States) was reported in 2012,[9] followed by multiple case series and registries reporting the feasibility of TAVI in NCAR with new-generation nondedicated devices. The most recent summary of the experience was reported in a meta-analysis by Takagi et al.,[10] and the pooled analysis at 30 days demonstrated 80.4% device success, 9.5% all-cause mortality, 7.4% ≥ moderate residual AR, and a pacemaker rate of 11.6%. Although these results were promising and significantly better than with early-generation devices in all aspects, there was still a substantial gap to achieve similar outcomes to TAVI in aortic stenosis and, indeed, the rate of valve embolization was high (above 9% with all the technologies, even the dedicated technologies).[10]

More recently, the new Myval balloon-expandable valve (Meril Lifesciences Ltd, Vapi, India) has demonstrated better outcomes than those reported by Takagi et al. likely due to the availability of extra-large sizes (30.5 and 32 mm), allowing a greater degree of oversizing and covering annuli up to 100.5 mm perimeter and 840 mm^2 area at its nominal volume, increasing the proportion of inoperable patients who can be treated percutaneously. Because

of the high procedural success rate (94.7%), and the absence of severe anatomical complications (ie, annular rupture, aortic dissection, or coronary obstruction), the Myval balloon-expandable valve is a promising new approach to this condition until dedicated devices for these annular sizes become available. Nevertheless, prosthesis embolization occurs in 3.5% of patients, leaving room for improvement; according to this research, the interplay of the aortic annulus and the LV outflow tract could help to predict the risk of valve embolization, suggesting that, in borderline annular sizes, when 20% oversizing cannot be achieved and adverse (tapered) morphology is detected, the intervention should be avoided or might be carried out under mechanical circulatory support (figure 1).[11]

Poletti et al.[12] recently compared latest-iteration nondedicated devices and suggested that Myval might provide the best outcomes compared with other devices; indeed, the subanalysis (not published yet) comparing the 2 balloon-expandable platforms suggested that, despite being used in patients with significantly smaller aortic annuli, SAPIEN-3 had a lower device success rate (72% vs 90%) and a higher rate of prosthesis migration/embolization (SAPIEN 17% vs MyVal 5%).[12] A summary of the PURE-AR study[11] with the Myval device is shown in figure 2. The current evidence on different devices is summarized in table 1.

In conclusion, although the surgical approach remains the standard-of-care in NCAR patients, the outcomes of new-generation dedicated and nondedicated TAVI devices are rapidly improving. The main caveats include the lack of large-sized dedicated devices and
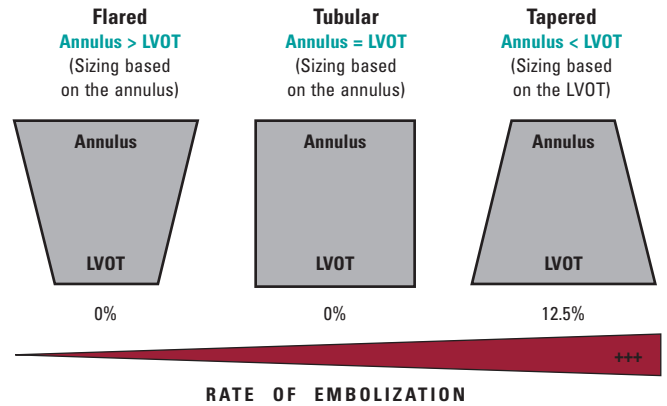
Figure 1. Anatomical predictor of valve embolization during transcatheter aortic valve implantation for noncalcified aortic regurgitation. LVOT, left ventricular outflow tract.

the risk of valve embolization with nondedicated devices, although this risk can be minimized by extra-large sizes and morphological analysis of the LV outflow tract. The rate of conduction disturbances is still higher than for TAVI in aortic stenosis and its decrease will require specific technology and strategies, given its potentially negative impact in LV remodelling. Clinical trials comparing surgery and TAVI in this setting for high-risk patients are an urgent need.

Figure 2. Main outcomes reported in the Myval registry for treatment of noncalcified aortic annuli with large annuli. AR, aortic regurgitation; LVOT, left ventricular outflow tract; TAVR, transcatheter aortic valve regurgitation.

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Table 1. Comparison of outcomes between the international registries

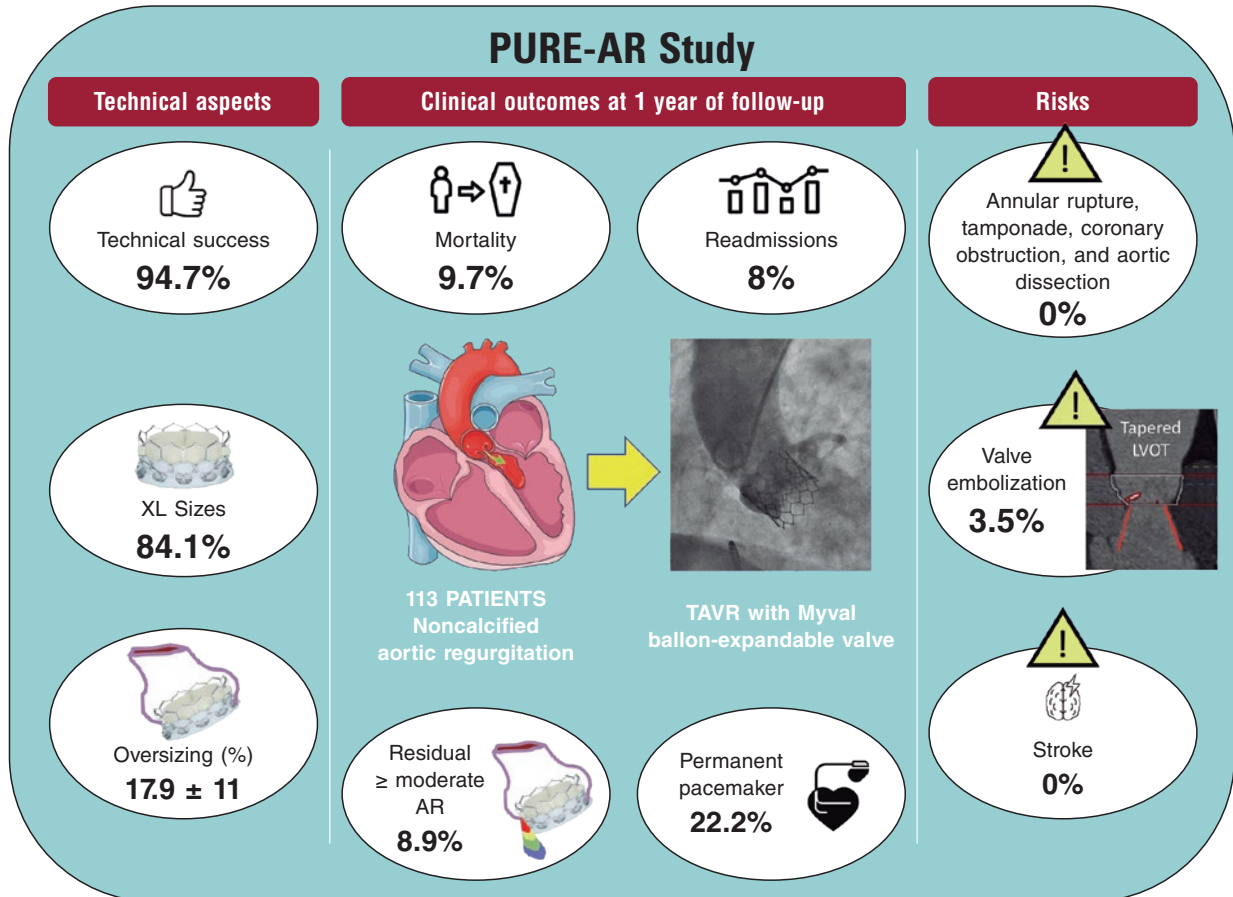| Registry	No. of patients	Type of device	Device success	All-cause mortality	≥ Moderate residual aortic regurgitation	Permanent pacemaker implantation rate
Yoon et al.[13] (2017)	331 patients with NCAR and FSHV	Nondedicated devices	Overall: 74.3%	Overall: 10.9%	Overall: 9.6%	Overall: 18.2%
		Early-generation devices (CoreValve, SAPIEN XT)	Early-generation devices: 61.3%	Early-generation devices: 13.4%	Early-generation devices: 18.8%	Early-generation devices: 17.5%
		New-generation devices (Evolut R, JenaValve, Engager, Portico, ACURATE, Lotus, Direct Flow, SAPIEN 3)	New-generation devices: 81.1%	New-generation devices: 9.4%	New-generation devices: 4.2%	New-generation devices: 18.6%
De Backer et al.[14] (2018)	254 patients with NCAR	Nondedicated devices Early-generation devices (CoreValve, SAPIEN XT)	Early-generation devices: 47%	Early-generation devices: 17%	Early-generation THV's: 26%	Not reported
		New-generation devices (Evolut R, JenaValve, Engager, Portico, ACURATE, Lotus, Direct Flow, SAPIEN 3)	Newer-generation devices: 82%	Newer-generation devices: 8%	Newer-generation THV's: 5%	
Sawaya et al.[15] (2018)	146 patients with NCAR and failing surgical heart valves (FSHV)	Early-generation devices (CoreValve SAPIEN XT)	NCAR: 72%	NCAR: 13%	NCAR: 13%	NCAR: 18%
		New-generation devices (Evolut R, JenaValve, Lotus, Direct Flow, SAPIEN 3)	FSHV: 71%	FSHV: 6%	FSHV: 6%	FSHV: 5%
			Early-generation devices: 54%	Early-generation devices: 22%	Early-generation devices: 27%	
			New-generation devices: 85%	New-generation devices: 8%	New-generation devices: 3%	
Sánchez-Luna et al.[11] 2023	113 patients with NCAR	New-generation nondedicated device: Myval	94.7%	9.7%	8.9%	22.2%
Poletti et al.[12] 2023	201 patients with NCAR	New-generation devices: SEV (Evolut R/Pro, ACURATE Neo/Neo2, Jena Valve, Navitor/Portico)	Overall: 76.1%	Overall: 5%	Overall: 9.5%	Overall: 22.3%
			SEV: 75.8%	SEV: 5.3%	SEV: 9.2%	SEV: 22.6%
		BEV (SAPIEN, Myval)	BEV: 76.8%	BEV: 4.4%	BEV: 10.1%	BEV: 21.8%
Adam et al.[6] (2023)	58 patients with NCAR	Dedicated device: Trilogy system (JenaValve)	98%	1.7%	0%	19.6%
Garcia S et al.[7] (2023)	27 patients with NCAR	Dedicated device: J-Valve	81%	3.7%	0%	13%

BEB, balloon-expandable valve; FSHV, failing surgical heart valve; NCAR, noncalcified aortic regurgitation; SEV, self-expandable valve; THV, transcatheter heart valve.
Medtronic, United States: CoreValve, Engager, and Evolut R. Edwards Lifesciences, United States: SAPIEN XT, SAPIEN 3. Abbott Vascular, United States: Navitor/Portico. Meril Life, India: Myval. Boston Scientific, United States: ACURATE Neo/Neo2, Lotus. Trilogy, Germany: JenaValve. Direct Flow Medical, United States: Direct Flow. JC Medical, United States: J-Valve.

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AUTHORS' CONTRIBUTIONS

CONFLICTS OF INTEREST

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Original article

The MANTA vascular closure device in transfemoral TAVI: a real-world cohort

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ABSTRACT

Introduction and objectives: Transcatheter aortic valve implantation (TAVI) is an established treatment option for patients with symptomatic severe aortic stenosis often performed via transfemoral access route (TF-TAVI). Therefore, successful closure of large-bore access sites is essential. This study aims to investigate the safety and effectiveness of the MANTA (Teleflex/Essential Medical, United States) vascular closure device (VCD) in patients undergoing TF-TAVI in an unselected and consecutive cohort of patients.

Methods: We conducted a single-center, observational study of 245 consecutive patients undergoing TF-TAVI in whom the arterial large-bore femoral access was closed with a MANTA device from March 2020 through February 2022. The primary efficacy outcome measure was the rate of VCD failure according to the VARC-3 definition.

Results: Successful closure of the large-bore access site occurred in 92.2% of the patients (n = 226). According to the VARC-3 definition, no major vascular or bleeding complications related to the plug-based VCD were reported. Patients with failed VCDs (7.8%) had significantly smaller minimal femoral artery diameters (6.6 ± 1.1 mm vs 7.6 ± 1.4 mm; *P* = .005) and consequently, significant higher sheath-to-femoral artery diameter ratios (0.78 ± 0.16 vs 0.69 ± 0.15; *P* = .019). No other inter-group differences were found.

Conclusions: In this single-center, real-world, unselected large cohort of consecutive patients treated with TF-TAVI, a plug-based VCD for large-bore arteriotomy closure turned out effective and safe, and enabled arterial access-site management with a low rate of complications.

Keywords: Aged. Aortic valve stenosis. Transcatheter aortic valve implantation. Vascular closure devices.

El dispositivo de cierre vascular MANTA en TAVI transfemoral: una cohorte del mundo real

RESUMEN

Introducción y objetivos: El implante percutáneo de válvula aórtica (TAVI) es una opción de tratamiento establecida para pacientes con estenosis aórtica grave sintomática, generalmente realizado por acceso transfemoral (TAVI-TF). Por lo tanto, el cierre exitoso de los sitios de acceso de gran calibre es esencial. Este estudio tiene como objetivo investigar la seguridad y la eficacia del dispositivo de cierre vascular (DCV) MANTA (Teleflex/Essential Medical, Estados Unidos) en pacientes tratados con TAVI-TF en una cohorte consecutiva y no seleccionada.

Métodos: Se realizó un estudio observacional de un solo centro, con 245 pacientes consecutivos tratados con TAVI-TF en quienes el acceso femoral arterial de gran calibre se cerró con MANTA, entre marzo de 2020 y febrero de 2022. La medida de resultado de eficacia primaria fue la incidencia de fallo del DCV usando la definición VARC-3.

Resultados: En el 92,2% (n = 226) de los pacientes se logró el cierre exitoso del sitio de acceso de gran calibre. De acuerdo con la definición VARC-3, no se informaron complicaciones vasculares ni hemorrágicas importantes relacionadas con el DCV basado en tapón. Los pacientes con fallo del DCV (7,8%) tenían un diámetro mínimo de la arteria femoral significativamente más pequeño (6,6 ± 1,1 frente a 7,6 ± 1,4 mm; p = 0,005) y, en consecuencia, una relación significativamente mayor entre el diámetro de la vaina y la arteria femoral (0,78 ± 0,16 frente a 0,69 ± 0,15; p = 0,019). No se encontraron otras diferencias entre los grupos.

Conclusiones: En esta gran cohorte no seleccionada de un solo centro, del mundo real, de pacientes con TAVI-TF consecutivos, un DCV basado en tapón para el cierre de la arteriotomía de gran calibre fue eficaz y seguro, lo que permitió el manejo del sitio de acceso arterial con una baja tasa de complicaciones.

Palabras clave: Edad avanzada. Estenosis de válvula aórtica. Reemplazo de válvula aórtica transcatéter. Dispositivos de cierre vascular.

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is an established treatment option for patients with severe symptomatic aortic stenosis,[1] especially those at high surgical risk[2] (also those at low and intermediate risk), and is often performed via transfemoral access route (TF-TAVI).[1] However, TF-TAVI access requires large-bore catheters (5 mm to 7 mm) and their management is responsible for a significant number of TAVI-related adverse events. Complications can affect between 5% and 20% of the patients,[3] and impact short- and long-term clinical outcomes.[3-5] Therefore, successful closure of large-bore access sites remains essential.[6,7]

During the early years of TF-TAVI, the femoral artery was closed surgically.[2] More recently, this method has been replaced by the use of suture-based vascular closure devices (VCD)[1] like the Perclose ProGlide VCD (Abbott Vascular, United States).[1,8] Although this closure technique proved to be a safe and effective first-line strategy for large-bore arterial access,[1] major vascular complications occurred in up to 5% of patients mainly due to failed arteriotomy closure devices.

MANTA (Teleflex/Essential Medical, United States) is a plug-based VCD that has shown promising results in TF-TAVI.[2,9-14] This device is dedicated to large-bore vessel closure and built on a proven concept of an intra-arterial toggle and extra-arterial collagen plug.[5,15] Early feasibility trials have reported encouraging safety and efficacy outcomes in a variety of procedures requiring large-bore vascular access.[1,9,11,16] Also, registry-based studies have demonstrated equivalence to suture-based techniques.[1,17] However, data regarding vascular complications and device failure rates compared to the well-known suture-based VCDs are scarce.[2] Recent studies, including small, selected patient cohorts concluded that compared to suture-based VCDs, plug-based VCDs were associated with significantly shorter lengths of stay following the procedure,[1,7] and less VCD failure.[1,5,7] No significant differences regarding mortality, bleeding or vascular complications were ever reported.[7]

This single-center study aims to investigate the safety and effectiveness of the MANTA VCD in patients undergoing TF-TAVI in an unselected and consecutive cohort of patients. We hypothesize that arterial closure with MANTA is associated with a high feasibility and low risk of major vascular and bleeding complications.

METHODS

Study design

This single-center observational, and retrospective study included a total of 245 consecutive patients who underwent TF-TAVI and in whom the MANTA device was used to close the arterial large-bore femoral access from March 2020 through February 2022 (figure 1). All patients had symptomatic severe aortic stenosis. Eligibility for TF-TAVI procedure was assessed by the heart team. The study was approved by the regional Human Research Ethics Committee (HREC) at Coimbra, Portugal. Informed consent was waived.
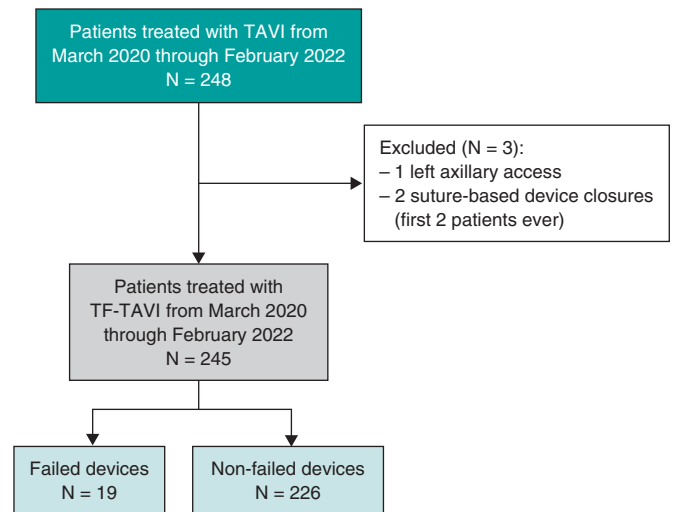
Figure 1. Central illustration. Flowchart of the patients incuded. TAVI, transcatheter aortic valve implantation; TF-TAVI, transfemoral transcatheter aortic valve implantation.

Demographics, preoperative, intraoperative, and postoperative data were collected from medical records.

Study outcomes

The study primary efficacy outcome measure was the rate of device failure according to the Valve Academic Research Consortium 3 (VARC-3) definition.[18] Device failure was defined as failure to successfully achieve hemostasis at the access site, thus leading to alternative treatment (surgery, balloon or covered stent).

The study secondary outcome was safety. Here we assessed the rate of VARC-3 major vascular and bleeding complications associated with the access site. Major vascular complications are lesions (perforations, ruptures, dissections, stenoses, ischemias, arterial thromboses, arteriovenous fistulas, pseudoaneurysms, hematomas, retroperitoneal hematomas, infections) resulting in death, VARC type ≥ 2 bleeding, limb or visceral ischemia or irreversible neurological impairment; distal embolization (noncerebral) from a vascular source resulting in death, amputation, limb or visceral ischemia or irreversible end-organ damage; unplanned endovascular or surgical intervention resulting in death, VARC type ≥ 2 bleeding, limb or visceral ischemia or irreversible neurological impairment. A major bleeding is considered type 2 if an overt bleeding requires the transfusion of 2–4 units of whole blood/red blood cells or else in the presence of an overt bleeding associated with a drop of hemoglobin levels from 3 g/dL to 5 g/dL; type 3 if bleeding is life-threatening, and type 4 if it leads to death.

As exploratory endpoints, we also evaluated cardiovascular and non-cardiac mortality during the index hospitalization and at 30-day follow-up.

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Procedural details

Before TF-TAVI, all patients underwent an echocardiogram, blood tests, and a multi-detector computed tomography according to the TAVI protocol using a dedicated software (3mensio, Maastricht, The Netherlands). Multi-detector computed tomography was performed to assess iliofemoral arteries for vascular access prior to the procedure. The size of the vessel, tortuosity, amount of calcification, and minimal lumen diameter were all analyzed. Calcification and tortuosity were separately scored by consensus visual analysis of 2 observers who were blind to the remaining patient data. The sheath-to-femoral artery diameter ratios were analyzed too. Anticoagulant and antiplatelet therapies according to the guidelines: if the patient was on anticoagulation, he didn't use the anticoagulant the day before and resumed it on the day of the procedure (in the absence of bleeding complications); if on antiplatelet therapy, single antiplatelet therapy was used; if not on anticoagulant or antiplatelet agent, an aspirin loading dose was used before the procedure followed by a single antiplatelet therapy agent. All procedures were performed under conscious sedation. Puncture of the femoral artery was performed with ultrasound guidance. During the procedure, heparin was administered and an activated clotting time between 250 s and 300 s was targeted. The bioprosthetic valves implanted were the CoreValve Evolut R/Pro (Medtronic, United States), ACURATE neo (Boston Scientific, United States), SAPIEN (Edwards Lifesciences, United States), and Navitor (Abbott, United States). After valve implantation, in cases where the activated clotting time was > 200 s, protamine sulfate was given before vascular closure.

MANTA device

The MANTA VCD is a collagen-based technology available in 2 sizes: 14-Fr and 18-Fr. It can be used for sheath sizes that go from 10-Fr to 14-Fr, and 15-Fr to 22-Fr, respectively. In brief, arteriotomy depth is determined with a centimeter-marked sizing tool before large-bore sheath insertion. At the end of the procedure, the large-bore sheath is exchanged for the dedicated MANTA sheath to accomodate the toggle–plug assembly. Afterwards, the anchor is opened 1.5 cm more than the femoral arterial wall-skin distance. The sheath is then removed, and the puncture site sandwiched between toggle and collagen that remain connected by a stainless-steel lock. Hemostasis success after the use of the MANTA VCD was evaluated through an angiography after vascular closure. As a standard practice, we typically use the contralateral femoral artery as a backup access, but do not routinely use a protection guide. In situations where access to the main site is necessary, we use a 0.035 in Glidewire Advantage guidewire that is advanced through the pigtail situated in the contralateral femoral artery and placed under the balloon. In the presence of bleeding complications that are not resolved by prolonged balloon inflation, a covered stent is often implanted.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation if normally distributed or as median [interquartile range] if not. Normality was checked using the Shapiro–Wilk test and histogram observation. Categorical data were expressed as numbers and percentages and compared using Pearson's chi-square test or Fisher's exact test, when appropriate. Continuous variables were compared using the Student t test. Formal tests for interaction were performed using logistic regression. Statistical significance was always set at a 2-tailed probability level of < 0.05. Statistics were performed using SPSS version 28 (IBM, United States).

Table 1. Baseline characteristics

General characteristics	N = 245
Age, years	81 ± 6
Female sex	132 (52.7)
BMI, kg/m²	27 ± 4.8
NYHA	
II	134 (54.7)
III-IV	111 (45.3)
NT-proBNP (pg/mL)	2197 (884-5545)
LVEF	53 ± 11
EuroSCORE II, %	3.15 (2.07-4.75)
Aortic valve MG, mmHg	48 ± 15
AVA, cm²	0.67 ± 0.17
Antiplatelet therapy	78 (31.8)
Anticoagulant therapy	87 (35.5)
Femoral artery characteristics (MANTA side)	
Minimal diameter – mm	7.5 ± 1.4
Calcification	
None	24 (10.4)
Mild	143 (61.9)
Moderate	44 (19.0)
Severe	20 (8.7)
Tortuosity	
None	137 (59.1)
Mild	70 (30.2)
Moderate	17 (7.3)
Severe	8 (3.4)

AVA, aortic valve area; BMI, body mass index; LVEF, left ventricular ejection fraction; MG, mean gradient; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association.
Data are expressed as no. (%), mean ± standard deviation or median [interquartile range].

RESULTS

Baseline characteristics

A total of 245 of consecutive patients treated with TF-TAVI whose arterial large-bore femoral access was closed with the MANTA 18-Fr VCD were included in our study. The baseline characteristics are shown on table 1. The population mean age was 81 ± 6 years with a median EuroSCORE II of 3.15% [2.07%-4.75%]. Most patients were women (53.9%). The Evolut R/Pro valve was implanted in > 50% of the cases (52.7%).

Primary outcome: efficacy of the MANTA plug-based vascular closure device

Successful closure of the large-bore access site occurred in 92.2% of the patients (n = 226). The main access artery was the right

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Table 2. Procedural characteristics

Procedural characteristics	N = 245
Valves	
ACURATE neo2, Boston Scientific, United States	36 (14.7)
Evolut PRO, Medtronic, United States	129 (52.7)
Portico (Abbott, United States)	43 (17.5)
SAPIEN, Edwards Lifesciences, United States	37 (15.1)
Femoral sheaths (MANTA side)	
14-Fr	135 (55.1)
16-Fr	75 (30.6)
18-Fr	33 (13.5)
20-Fr	2 (0.8)
Sheath-to-femoral artery diameter ratio	0.69 ± 0.15

Data are expressed as no. (%) or mean ± standard deviation.

Table 3. Primary endpoint – efficacy

	N = 245
Device failure	19 (7.8)
Balloon	16 (6.5)
Balloon + covered stent	2 (0.8)
Surgical correction	1 (0.4)

Data are expressed as no. (%).

common femoral one in 90.6% of the patients (n = 222). The mean minimal femoral arterial diameter at the access site was 7.5 ± 1.4 mm (table 1). The mean sheath-to-femoral artery diameter ratio was 0.69 ± 0.15 (table 2). Only 1 out of the 19 patients with device failure (7.8%) required a secondary surgical approach (due to occlusion of the femoral artery unresolved with balloon dilatation) (table 3).

Secondary outcome: safety of the MANTA plug-based vascular closure device

According to the VARC-3 definition, no major vascular or bleeding complications associated with the plug-based device were reported. A total of 8.6% of all the patients included (n = 21) had a minor VARC-3 vascular complication (table 4). Two-thirds (n = 14) showed femoral artery stenoses, 23.8% (n = 5) hematomas, and 9.5% (n = 2) pseudoaneurysms associated with the common femoral artery. The rate of minor bleeding complications associated with the main access site (closed with MANTA) was 2.9% only (n = 7).

Predictors of device failure

Patients with device failure (7.8%) had a significant smaller minimal femoral artery diameter (6.6 ± 1.1 mm vs 7.6 ± 1.4 mm; *P* = .005) and consequently, significant higher sheath-to-femoral artery diameter ratios (0.78 ± 0.16 vs 0.69 ± 0.15; *P* = .019) (table 5). Patients with failed VCDs had more tortuous and calcified arterial accesses as shown on table 5. No other differences were found.

Table 4. Secondary outcome: safety

	N = 245
Bleeding complications: access site-related	7 (2.9)
Minor (VARC-1 type)	7 (2.9)
Major (VARC-2, -3 or -4 types)	0 (0.0)
Vascular complications: access site-related	21 (8.6)
Minor	21 (8.6)
Major	0 (0.0)

VARC, Valve Academic Research Consortium 3.
Data are expressed as no. (%).

In-hospital and short-term outcomes

Duringt the index hospitalization, 2 patients (0.8%) died of cardiovascular causes not associated with the VCD closure. One patient died due to aortic dissection and left ventricular rupture during the procedure despite conversion to open heart surgery. A second patient died following an ischemic stroke. The 30-day mortality rate was 3/245 (1.2%) because another patient died of urosepsis 14 days after discharge. Device failure did not extend the postoperative length of stay (median time to discharge, 4 days [3-5]).

DISCUSSION

This single-center study shows the real-world experience with the MANTA VCD for large caliber arteriotomy closure in an unselected consecutive cohort of patients referred for TF-TAVI. Our results, in an older and more frail population compared to RCT[1,5] [with a EuroSCORE II of 3.15% (2.07-4.75), higher than the 2.6% (1.9-3.6) of the MASH trial, but lower than the 4.5 ± 4.8% of the CHOICE-CLOSURE] demonstrate a low MANTA device failure rate of 7.8% with no major device-related bleeding or vascular complications.

Compared to the most recent RCTs (MASH[5] and CHOISE-CLO-SURE[1] trials) that included 216 and 510 patients, respectively, our results showed a lower rate of device failure with the MANTA device compared to the MASH trial (7.8% vs 20%), but > 4.7% compared to the CHOISE-CLOSURE,[1,5] and 5.2% in a recent meta-nalysis.[19] However, in the latter trial, authors did not consider balloon dilatation bailout as device failure, which may explain the lower failure rate of the plug-based VCD while we used balloon dilatation in most devices failures (16 out of 19 failures).

The high success rate of the MANTA device (92.2%) is probably due to our extensive experience with this type of device. Since the beginning of the TAVI program, this has been the most widely used VCD, which differentiates us from former studies. Furthermore, all TF-TAVIs were performed by a small group of 3 experienced operators with a large volume of vascular closure cases using this device. Conversely, in the MASH trial, MANTA was introduced later in the clinical practice and, consequently, experience was more limited.[5] Compared to suture-based large-bore arteriotomy closure, the MANTA device showed less device failure and shorter time to hemostasis in both trials.[1,5]

We did not report any major vascular or bleeding complications associated with the MANTA VCD unlike RCTs[1,5] and the most recent observational study. Still, this last study used VARC-2 criteria to define major complications.[20] Halim et al.[2] showed rates of minor vascular and bleeding complications of 13.7% and 5.5%,

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Table 5. Failed device vs non-failed device

	Failed device (N = 19)	Non-failed device (N = 226)	Odds ratio	95%CI	P
Minimal femoral artery diameter, mm	6.6 ± 1.1	7.6 ± 1.4	0.56	0.37-0.84	.005
Sheath-to-femoral artery ratio	0.78 ± 0.16	0.69 ± 0.15	32	1.78-579.48	.019
Body mass index, kg/m²	27 ± 6	27 ± 5	0.99	0.89-1.09	.769
Postoperative length of stay, days	4 [3-5]	4 [3-5]	-	-	.728
Moderate-to-severe tortuosity	57.9	13.1	9.1	3.35-24.90	< .001
Moderate-to-severe calcification	52.6	22.7	2.9	1.12-7.49	.028
Anticoagulation therapy at baseline	31.6	35.8	0.83	0.30-2.26	.71
Antiplatelet therapy at baseline	31.6	31.9	0.99	0.36-2.70	.98

Data are expressed as %, mean ± standard deviation or median [interquartile range].

respectively, almost doubling those of our cohort (8.6% and 2.9%, respectively). As previously mentioned, this may be explained by our experience with this VCD. Another possible reason was that we were used to smaller plug-based devices like Angioseal.[1,9,16] Therefore, familiarity with this technique seems to facilitate short learning curves with the MANTA device.[1,13,14]

In the MASH and CHOISE-CLOSURE trials, patients whose large-bore arterial access site were closed with the MANTA device had more minor vascular and hemorrhagic complications compared to those whose access sites were closed with suture-based devices. However, they were not significantly different and no differences in major complications were ever reported. This fact can be explained by the greater knowledge and experience using the ProGlide VCD by these teams.[1,5] In a meta-analysis that compared MANTA vs suture-based VCD[7] the authors conclude that plug-based vascular closure with MANTA was associated with fewer chances of device failure following large-bore arteriotomy procedures without significant differences being reported in bleeding or vascular complications compared to suture-based closure devices.

Although recommendations[21] tell us that we should not use the MANTA device in vessels with minimum diameters < 6 mm, some of our patients had lower values. The main reason observed for VCD-related adverse vascular events was common femoral artery stenosis due to poor toggle positioning in smaller femoral arteries. This has been previously reported in the medical literature.[22] Therefore, the implantation of MANTA in smaller femoral arteries should be avoided. Thus, as expected, those with device failure had a significantly smaller minimal femoral diameter, higher sheath-to-femoral artery diameter ratios, and more tortuous and calcified arterial accesses.

A recent study[23] showed that when ultrasound was used to guide MANTA implantation, fewer vascular complications and device failure were reported perhaps because ultrasound helps clinicians choose the best site, thus avoiding calcium plaques and confirming the anchor in the proper position and the collagen pad delivered to the vessel wall through subcutaneous tissue. We had already used ultrasound to guide femoral access, which may explain our low rate of vascular complications. However, if in the future we also guide the deployment of MANTA, it can be possible to further reduce device failure not associated with postoperative length of stay or mortality as in former studies.[1,5,7] We had a lower rate of in-hospital mortality (0.8%) compared to the 1.5% of the CHOICE-CLOSURE trial. No deaths were associated with the MANTA device.[1,5]

As far as we know, this is the largest real-world study ever conducted using MANTA to close large-bore femoral arterial accesses after TF-TAVI whose primary outcome was device efficacy using the VARC-3 criteria. The MANTA device shows promising results with low rates of vascular/bleeding complications and device failure without compromising the length of stay or the in-hospital/short-term mortality in the real-world setting. The shorter learning curve compared to suture-based VCDs is another plus. Therefore, the MANTA device could become the preferred option for large-bore vascular closure in TF-TAVI. The ultrasound-guided implantation of MANTA seems to be a solution for the complications and device failure seen in these patients. Thus, futures studies must compare the efficacy and safety profile of suture-based VCDs and ultrasound-guided plug-based VCDs in the real-world setting.

Limitations

This was a retrospective study and a single-center experience where we did not compare the plug-based VCD to another closure system. Therefore, it may be subject to different biases. Finally, our study did not perform postoperative ultrasounds in all patients. Therefore, we could have left out the asymptomatic vascular complications despite the angiographies performed after the procedure. However, no clinical impact was seen at follow-up of the putative asymptomatic vascular complications.

CONCLUSIONS

In this single-center, real-world, unselected and consecutive large cohort of patients treated with TF-TAVI, a plug-based VCD for large-bore arteriotomy closure turned out effective and safe, and enabled arterial access-site management with a low rate of complications. Smaller minimal femoral artery diameters and higher sheath-to-femoral artery diameter ratios were associated with a higher risk of failed VCDs.

FUNDING

ETHICAL CONSIDERATIONS

The study was approved by the regional Human Research Ethics Committee (HREC) at Coimbra, Portugal. Informed consent was

waived. The authors confirm that variables such as sex and gender were taken into account in accordance with SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence was not used for the development of this work.

AUTHORS' CONTRIBUTIONS

Study design, data collection and review, statistical analysis, and manuscript preparation: S. Martinho, E. Jorge, A. Vera Marinho, R. Baptista, M. Costa, and L. Gonçalves; Coordination and document submission: S. Martinho. All authors reviewed and approved the final version of the manuscript.

CONFLICTS OF INTEREST

None reported.

WHAT IS KNOWN ABOUT THE TOPIC?

– TF-TAVI access requires large-bore catheters. Therefore, successful closure of large-bore access sites is essential. Previously, MANTA showed promising results in TF-TAVI.

– Data regarding the rates of vascular complications and device failure with MANTA compared to the well-known suture based VCDs are scarce.

WHAT DOES THIS STUDY ADD?

– This is the largest real-world study of MANTA devices ever conducted to close the large-bore femoral arterial access after TF-TAVI. The study primary outcome was device efficacy using the VARC-3 criteria.

– The MANTA device shows promising results with low rates of vascular/bleeding complications and device failure without compromising the length of stay or the in-hospital/short-term mortality in a real-world setting. It proved to be easy to use.

– Our results may encourage the use of this VCD as a first option to close large caliber arterial vessels given its consistent efficacy and safety profile.

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Original article

Transcatheter aortic valve implantation via percutaneous alternative access routes: outcomes

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ABSTRACT

Introduction and objectives: Transfemoral access is globally accepted as the preferential access route for transcatheter aortic valve implantation (TAVI). However, in up to 15% of the patients, this access is considered inadequate. Considering the various alternatives available, the fully percutaneous access routes have been chosen preferentially. This analysis aims to compare outcomes and complications of 3 alternative access routes for transfemoral, trans-subclavian and transcaval TAVI.

Methods: Retrospective analysis of patients referred for TAVI using transfemoral, trans-subclavian, and transcaval accesses in a single tertiary center from 2008 through 2021. The primary endpoints were 30-day and 1-year all-cause mortality rates. The secondary endpoints were technical success, residual moderate-to-severe paravalvular leak, major vascular complication, 30-day stroke, 30-day Valve Academic Research Consortium-2 (VARC-2) major bleeding, and 30-day acute kidney injury (AKIN criteria 2 or 3).

Results: A total of 642 TAVIs were performed (601 transfemoral, 24 trans-subclavian, and 10 transcaval). A total of 7 patients treated via transapical access were excluded. As expected, baseline comorbidities like left ventricular dysfunction, coronary artery disease, atrial fibrillation, chronic kidney disease, and previous stroke were more frequent in the non-femoral groups. The 1-year and 30-day all-cause mortality rates were higher in the non-transfemoral population (HR, 2.88 and HR, 3.53, respectively). The rates of 30-day stroke and acute kidney injury (AKIN 2 or 3) were also significantly lower in transfemoral patients, but similar between trans-subclavian and transcaval patients. The rates of 30-day major bleeding showed a statistically significant tendency towards lower rates in the transfemoral group. The rates of technical success, major vascular complications, and residual moderate or severe perivalvular leak were similar among the 3 groups.

Conclusions: After careful selection, transfemoral access is the preferential access route for TAVI procedures. In intermediate surgical risk patients with severe symptomatic aortic stenosis, non-transfemoral TAVI approaches have poorer outcomes. The worse outcomes of percutaneous alternative access routes are partially associated with worse baseline characteristics.

Keywords: Transcatheter aortic valve implantation. Transfemoral. Trans-subclavian. Transcaval.

Implante percutáneo de válvula aórtica a través de accesos percutáneos alternativos: resultados clínicos

RESUMEN

Introducción y objetivos: El acceso transfemoral (aTF) es el de elección para el implante percutáneo de válvula aórtica (TAVI). Sin embargo, hasta en el 15% de los pacientes este acceso es inadecuado. De las alternativas disponibles, el acceso totalmente percutáneo es el preferido. El objetivo del estudio es comparar los resultados clínicos de los pacientes tratados por aTF frente a los de aquellos con acceso transubclavio (aTS) o transcava (aTCv).

Métodos: Análisis retrospectivo de los pacientes tratados con TAVI (2008-2021) en un centro terciario mediante aTF, aTS y aTCv. El objetivo primario fue la mortalidad por cualquier causa a 30 días y 1 año. Los objetivos secundarios fueron el éxito técnico, la regurgitación perivalvular moderada o grave, las complicaciones vasculares mayores, el accidente vascular cerebral, el sangrado mayor y el daño renal agudo a 30 días (Valve Academic Research Consortium II [VARC-2]).

Resultados: Se realizaron 642 TAVI (601 por aTF, 24 por aTS y 10 por aTCv). Fueron excluidos 7 pacientes tratados por vía transapical. En los pacientes con acceso alternativo fue más frecuente la comorbilidad, incluyendo disfunción ventricular izquierda, enfermedad coronaria, fibrilación auricular, enfermedad renal e ictus previo. La mortalidad a 1 año y a 30 días fue también más

alta en este grupo de pacientes (*hazard ratio* [HR] = 2,88 y 3,53, respectivamente). A 30 días, las tasas de ictus y daño renal (grado 2 o 3) fueron significativamente más bajas para el aTF, y similares en los pacientes con aTS y aTCv. Hubo también una tendencia a menor sangrado en el grupo de aTF. El éxito técnico, las complicaciones vasculares mayores y la regurgitación perivalvular moderada o grave fueron similares en los tres grupos.
Conclusiones: Tras una adecuada selección, el aTF es el preferido para el TAVI. En pacientes de riesgo intermedio con estenosis aórtica grave sintomática, un acceso no transfemoral tiene peores resultados. Los inferiores resultados del uso de vías percutáneas alternativas están parcialmente relacionados con las peores características clínicas basales.

Abbreviations

TAVI: implante percutáneo de válvula aórtica.

INTRODUCTION

Transfemoral access is globally accepted and advised by international guidelines as the preferred approach for transcatheter aortic valve implantation (TAVI).[1-2] Despite the experience with this technique and miniaturization of the latest generation transcatheter heart valves (currently using 14-Fr-to-16-Fr sheaths), registries describe that trans-femoral access simply cannot be used in about 15% to 20% of the patients, mainly due to heavily calcified peripheral arterial disease or unfavorable anatomy.[3] Surgical access like the transapical and transaortic approaches are progressively being withdrawn due to their invasiveness and poor outcomes.[4] To this date, no randomized clinical trials have been conducted comparing the different alternative percutaneous approaches (trans-subclavian, transcarotid, and transcaval) so their use depends on the center experience and the learning curve.[5] Also, some approaches may be preferred in some patients depending on their comorbidities and vascular anatomy.

The trans-subclavian approach was first developed with a surgical exposure of the artery. However, more recently, a fully percutaneous trans-subclavian approach has been performed proving safe and feasible, making it potentially the second-line access following the transfemoral one. However, it may be contraindicated in the presence of vascular stenosis, tortuosity, increased angulation, and coronary artery bypass graft surgery using internal mammary artery grafts.[6] The transcaval approach is the latest technique to be developed. It avoids the morbidity associated with the transthoracic surgical approach, and provides the same room ergonomics compared to transfemoral access, as well as the possibility of larger introducer sheaths via venous access without a higher risk of major bleeding.[7] It requires a favorable abdominal anatomy and a very precise computed tomography scan to plan cavo-aortic puncture and aortic wall occlusion after delivery.[8]

Purpose

This analysis aims to compare the outcomes and complications of transfemoral, trans-subclavian, and transcaval access routes for TAVI.

METHODS

Patient selection

All patients referred for TAVI to a single tertiary center from 2008 through 2021 were included in this analysis. The transfemoral access was always considered the default access route. In patients in whom this access route was not possible, the alternative access route was decided by a heart team based on other clinical and anatomical features (calcified disease or extreme tortuosity of subclavian arteries, presence of a left internal mammary artery bypass graft, arteriovenous fistula in patients on hemodialysis, severe calcified abdominal aorta or other unfavorable conditions for cavo-aortic puncture. This analysis was approved by the center ethics committee and informed consent was obtained from all the patients.

Procedural protocol

Based on the center protocol, before TAVI, all patients underwent a transthoracic echocardiogram, a 12-lead electrocardiogram, lab tests, an invasive coronary angiography, and a preoperative computed tomography scan.

Regarding the trans-subclavian access, the left subclavian artery was often chosen due to its more favorable orientation unless the patient had a left internal mammary artery bypass graft. In the early cases, the artery used to be surgically exposed by a vascular surgeon but then the technique evolved to a fully percutaneous approach using Seldinger technique. In our own experience the subclavian artery hemostasis was achieved in all cases with suture-mediated closing devices (ProGlide).

Regarding the transcaval access, both a right femoral vein, and a left femoral artery (for secondary access) were used. Via femoral artery a pigtail catheter is initially advanced to perform an abdominal aorta angiography to later place it in the target entry site. Via femoral vein, using the telescope technique, a stiff 0.014 in coronary guidewire (Astato) is advanced inside a micro-guide catheter (FineCross) that is inside a 0.035 micro-guide catheter (NaviCross). Cavo-aortic puncture and crossing are performed with electrification of the guidewire and guidance of a snare placed in the abdominal aorta. The whole system is advanced from the inferior vena cava to the abdominal aorta allowing change to a 0.035 stiff guidewire (Lunquerquist). Afterwards, the sheath delivery system can be advanced over the wire, and the valve is implanted according to the standard technique. After valve implantation, the aortic wall defect is closed with an occlusion device (Amplatzer Duct Occluder). All patients were followed with regular visits 1, 3, and 12 months after TAVI, and thereafter yearly or with other periodicity based on assistant cardiologist decision.

Table 1. Baseline characteristics

Baseline characteristic	Overall TAVI population (635)	Transfemoral TAVI (601)	Non-transfemoral TAVI (34)	P
Age in years – mean ± SD	82.0 ± 6.4	82.2 ± 6.3	78.9 ± 7.0	**.004**
Gender (female)	57% (363)	59% (354)	27% (9)	**< .001**
Coronary artery disease	42% (265)	41% (246)	56% (19)	.093
Previous MI	16% (99)	16% (93)	18% (6)	.734
Previous CABG	14% (87)	14% (82)	15% (5)	.799*
Atrial fibrillation	34% (214)	33% (200)	41% (14)	.333
Previous stroke	11% (70)	10% (62)	24% (8)	**.019***
Diabetes	35% (225)	35% (213)	35% (12)	.986
CKD (KDIGO stage ≥ 3)	49% (311)	48% (290)	62% (21)	.127
Hemodialysis	4% (17)	4% (15)	8% (2)	.306*
Previous pacemaker	9% (58)	9% (54)	12% (4)	.540*
EuroSCORE II – mean [IQR]	6.77 (5.27)	6.72 (5.28)	7.77 (7.55)	.125
STS Score – mean [IQR]	6.20 (3.87)	6.25 (3.91)	5.16 (3.30)	.579
Basal NYHA class – mean ± SD	2.76 ± 0.54	2.76 ± 0.54	2.79 ± 0.64	.700
Mean aortic gradient – mean ± SD	50 ± 16	51 ± 16	47 ± 14	.151
PASP – mean ± SD	44 ± 14	44 ± 14	46 ± 17	.554
LVEF < 50%	22% (141)	22% (129)	35% (12)	.063
LVEF < 40%	12% (73)	11% (66)	21% (7)	.099*
Bicuspid aortic valve	3% (21)	3% (20)	3% (1)	.909*
AVCS – mean ± SD	2460 ± 1493	2448 ± 1488	2661 ± 1600	.475

AVCS, aortic valve calcium score; CABG, coronary artery bypass graft; CKD, chronic kidney disease; KDIGO, kidney disease improving global outcomes; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; TAVI, transcatheter aortic valve implantation; PASP, pulmonary artery systolic pressure; SD, standard deviation; STS, Society of Thoracic Surgeons.
* Fisher's exact test was used.

Statistical analysis

Patients were categorized based on the access route used and analyzed based on the baseline characteristics, procedural data, and outcomes. Continuous variables were expressed as mean and standard deviation (SD) or median and interquartile ranges [IQR] when normal or non-normal distributions of data were found, respectively. Categorical variables were expressed as as absolute (n) and relative frequency (percentage). Normal distribution was confirmed using the Kolmogorov-Smirnov test or skewness and kurtosis. Intergroup differences were tested with an independent sample t-test for continuous variables of normal distribution, and the Mann-Whitney test for continuous variables without a normal distribution. Chi-square and Fisher's exact test were used for categorical variables. The primary endpoints were evaluated using a Kaplan-Meier curve analysis and a Cox regression model for significant differences. Secondary outcomes were compared using Fisher's exact test. Statistical significance was defined as P values < .05. All tests were two-sided. The software used for statistical analysis was SPSS version 25.0 (SPSS Inc., United States).

Endpoints definition

The primary endpoint was all-cause mortality at 30 days and 1 year between patients treated with transfemoral and non-transfemoral

TAVI. Secondary outcomes included technical success, presence of residual moderate-to-severe paravalvular leak, major vascular complications, 30-day major bleeding, 30-day stroke assessed according to the VARC-2, and acute kidney injury (Acute Kidney Injury Network [AKIN] 2 or 3).

RESULTS

Population baseline characteristics

During the study period, 642 TAVIs were performed. A total of 7 patients were excluded from this analysis because their TAVI had been performed via transapical access. Of the remaining 635 ones, transfemoral, percutaneous non-transfemoral, trans-subclavian, and transcaval accesses were used in 601 (94.6%), 34 (5.4%), 24, and 10 patients, respectively. The baseline characteristics are shown on table 1. In the overall TAVI population, mean age was 82.0 ± 6.4 years old, and significantly lower in the non-transfemoral group. Women were much more prevalent in the transfemoral (57%) compared to the non-femoral group (30%). The severity of aortic stenosis was not significantly different among the subgroups of this analysis (mean gradient, 50mmHg; mean pulmonary artery systolic pressure, 44 mmHg; mean baseline New York Heart Association (NYHA) functional class, 2.76 ± 0.54; mean aortic valve calcium score by computed tomography of 2460 ± 1493 in the overall TAVI

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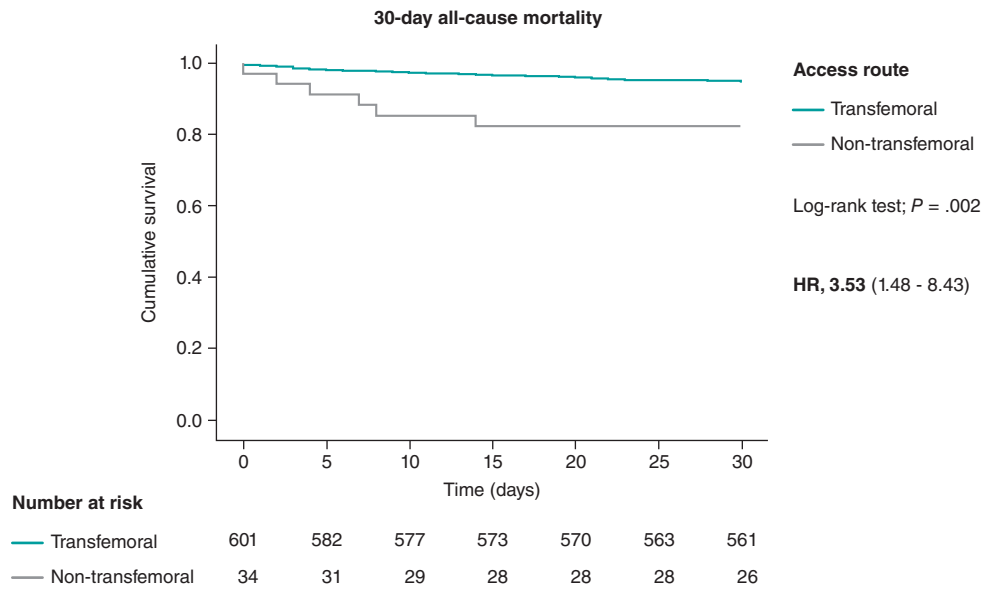
Figure 1. 30-day all-cause mortality Kaplan-Meier curve analysis between transfemoral and non-transfemoral TAVI patients. TAVI, transcatheter aortic valve implantation.
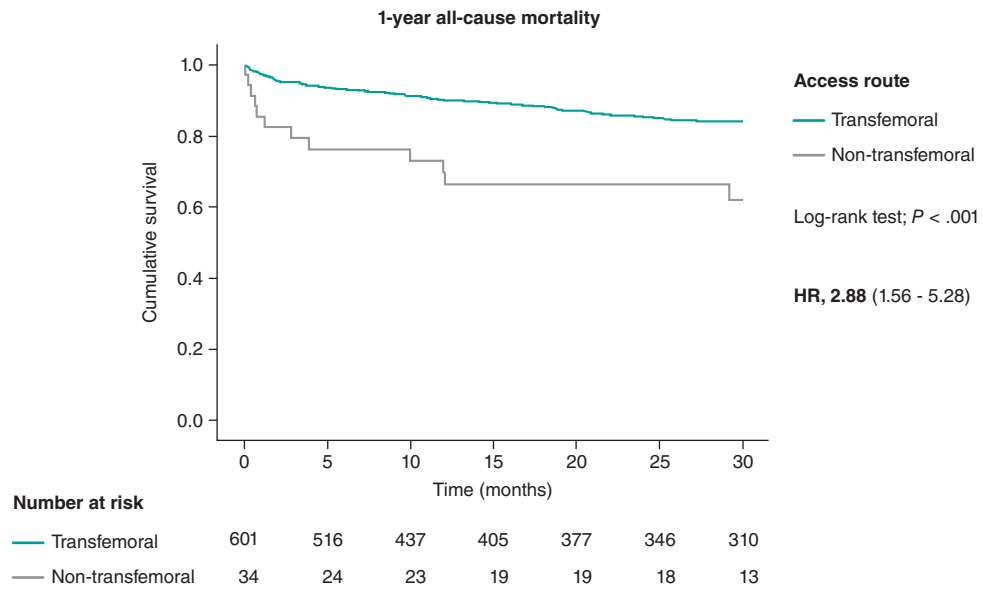
Figure 2. 1-year all-cause mortality Kaplan-Meier curve analysis between patients treated with transfemoral and non-transfemoral TAVI. TAVI, transcatheter aortic valve implantation.

population). However, the prevalence of, at least, moderate left ventricular dysfunction was higher in the non-femoral population (21% of the patients with left ventricular ejection fraction < 40% vs 12% in the overall group). The prevalence of bicuspid aortic valve was not significant among the different groups. Of note, the prevalence of coronary artery disease tends to be higher in the non-femoral group (56% vs 41%, *P* = .093, respectively) with an expected lower rate of previous coronary artery bypass graft in the trans-subclavian group because the presence of an left internal mammary artery graft may preclude the use of the left subclavian access. In the 2 cases reported of trans-subclavian access in patients with previous coronary artery bypass graft, the right subclavian access was used. Higher prevalence of known atrial fibrillation, previous stroke, and chronic kidney disease was noted in the

non-femoral group. EuroSCORE II and Society of Thoracic Surgery scores predicted statistically non-significant risks between both groups.

Primary endpoints

The 1-year and 30-day all-cause mortality rates were significantly higher in the non-transfemoral TAVI population with a hazard ratio of 3.53 (95% confidence interval [95%CI,1.48-8.43; *P* = .004) at 30 days, and 2.88 (95%CI, 1.56-5.28; *P* = .001) 1 year after TAVI. The highest mortality rate at 30 days after TAVI was seen in the transcaval population (30%) with no other deaths being reported within the first year after TAVI. In the trans-subclavian TAVI population,

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Table 2. Primary endpoints

Primary endpoints	Transfemoral TAVI (601)	Non-transfemoral TAVI (34)		P
		TS (24)	TCv (10)	
30-day all-cause mortality	5.4% (34)	17.6% (6)		.015[a]
		12.5% (3)	30.0% (3)	
1-year all-cause mortality	13.8% (82)	35,3% (12)		.001[b]
		37.5 % (9)	30.0% (3)	

TAVI, transcatheter aortic valve implantation; TCv, transcaval; TS, trans-subclavian.
[a] Fisher exact test.
[b] Chi-square test.

Table 3. Secondary endpoints

Secondary endpoints	Transfemoral TAVI (601)	Non-transfemoral TAVI (34)		P
		TS (24)	TCv (10)	
Technical success	94% (562)	94% (32)		.889*
		92% (22)	100% (10)	
Residual moderate-to-severe leak	3% (18)	0% (0)		.616*
		0% (0)	0% (0)	
Major vascular complication	6% (34)	9% (3)		.441*
		8% (2)	10% (1)	
30-day stroke	3.5% (21)	12% (4)		.039*
		13% (3)	10% (1)	
30-day major/life-threatening bleeding	10% (60)	21% (7)		.076*
		17% (4)	30% (3)	
30-day AKI (AKIN 2 or 3)	8% (48)	21% (7)		.022*
		21 % (5)	20% (2)	

AKIN, Acute Kidney Injury Network; TAVI, transcatheter aortic valve implantation; TCv, transcaval; TS, trans-subclavian.
* Differences studied using Fisher's exact test.

the mortality rate was high at 30 days (12.5%) and increased by a factor of 3 at 1 year (37.5%).

The 30-day and 1-year all-cause mortality Kaplan-Meier curves are shown on figure 1 and figure 2. Table 2 shows the mortality rates among the 3 groups of access routes for TAVI.

Secondary endpoints

The 30-day stroke and acute kidney injury (AKIN 2 or 3) rates were significantly lower in te transfemoral patients, but similar between trans-subclavian and transcaval patients. The 30-day rates of major bleeding showed a statistically significant tendency towards lower rates in the transfemoral group. The rates of technical success, major vascular complication, and residual moderate or severe para-valvular leak were similar among the 3 groups. Secondary endpoints are shown on table 3.

DISCUSSION

In this retrospective analysis, we show data on the comparison between transfemoral and non-transfemoral access routes for TAVI in a tertiary center. The registered non-transfemoral rate of 5.4% was far below the rates described in the medical literature available (from 15% to 20%),[3] which may be indicative of the recent developments and improvements made with TAVI sheaths and increasing technical experience gained leading to a lower need for alternative access routes in the current clinical practice. Nevertheless, this study shows that in high-volume centers, the number of patients with severe aortic stenosis who are ineligible for transfemoral TAVI remains a significant issue.

As expected, the transfemoral access route performed better than the alternative access routes regarding mortality rates, postoperative acute kidney injury and 30-day stroke and major bleeding events. No significant differences were seen regarding technical success, residual moderate-to-severe paravalvular leak or major vascular complications. This difference in outcomes can be explained, at least partially, by the dissimilar baseline characteristics. The primary and secondary endpoints were not significantly different between the trans-subclavian and the transcaval subgroups.

Without an interventional procedure being performed, severe aortic stenosis has poor prognosis, and a mortality rate somewhere around 50% at 2 years.[9] Early studies of fully percutaneous trans-subclavian and transcaval TAVI reported 30-day mortality rates of 6% and 8%, respectively,[6,7] higher than those reported for transfemoral TAVI. In addition, a systematic review of the medical literature available based on registries reported lower mortality rates for transfemoral TAVI vs other alternative access routes, at 30 days, with odds ratios (OR) of 0.56 and, at 1 year, and OR of 0.68 with similar rates of bleeding and cerebrovascular events.[10] Aside from this differences in in-hospital and 30-day mortality, trans-subclavian approach is also associated with higher rates of acute myocardial infarction (OR, 5.3), renal complications (OR, 2.3), and pacemaker implantation (OR, 1.6) compared to transfemoral TAVI.[11]

A different registry reports similar 30-day and 1-year survival rates among transfemoral, transcaval, and transcarotid TAVI.[12] These results were not found in our cohort probably due to the worse baseline characteristics and small number of transcaval procedures performed considering it's a complex technique with a considerable learning curve.

In our analysis, the mortality registered 1 year after TAVI with non-transfemoral access is close to the mortality rates of severe aortic stenosis treated medically, which raises questions on the futility of these procedures. Furthermore, as seen on the baseline characterization of the population, the mean EuroSCORE II and Society of Thoracic Surgery scores (7.77% and 5.16%, respectively) stratifies the non-femoral population globally as intermediate-risk for surgical aortic valve replacement, a therapeutic option with 1-year mortality rates around 11% in patients with intermediate surgical risk aortic stenosis.[13]

Regarding the comparison between trans-subclavian and transcaval accesses, a retrospective analysis of a large multicentric registry describes lower rates of stroke (OR, 0.20; P = .014) and similar rates of bleeding (OR, 0.66; P = .38) with transcaval compared to trans-subclavian access.[14] However, currently, there are no randomized data to support 1 specific alternative approach over the other. Hence, in patients with prohibitive transfemoral access route, vascular anatomy, risk factors, and the experience of the heart team should determine the preferred approach. Preoperative

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coronary computed tomography angiography plays a determinant role in the selection of the most appropriate alternative route as it allows us to accurately assess luminal diameters, vessels calcification, tortuosity and angulation, the previous use of 1 or 2 internal mammary arteries, and the aortic wall area eligible for cavo-aortic crossing.[15]

Limitations

This study has limitations associated with the nature of a non-randomized, retrospective, single center like selection bias. The extended period that was analyzed may also influence the results. In addition, the sample size in the transfemoral and transcaval subgroups is suboptimal, which limits the statistical analysis.

CONCLUSIONS

This analysis enhances the role of transfemoral access as the preferential access route for TAVI after careful patient selection. The trans-subclavian and transcaval approaches seem feasible with reasonable results. In intermediate surgical risk patients with severe symptomatic aortic stenosis, non-transfemoral TAVI has worse outcomes. The worse outcomes reported for percutaneous alternative access routes are partially associated with the worse baseline characteristics. In many of these patients, both the futility of the procedure and the experience of the heart team should be considered to determine the preferred approach. Further randomized clinical trials are needed to establish a preferential alternative access route in high surgical risk patients ineligible for transfemoral TAVI.

FUNDING

None whatsoever.

ETHICAL CONSIDERATIONS

The authors declare that this study was approved by the Institution and Institutional ethics committee.

Informed consent was obtained from all patients for the analysis and publication of their data.

Sex and gender variables have been taken into account in accordance with the SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence was not used for the development of this study or writing of the manuscript.

AUTHORS' CONTRIBUTIONS

A. Grazina, B. Lacerda Teixeira, A. Castelo, T. Mendonça, and I. Rodrigues collected and analyzed data. A. Grazina, and B. Lacerda Teixeira drafted the manuscript with support from R. Ramos, A. Fiarresga, L. Patrício, D. Cacela, and R. Cruz Ferreira.

CONFLICTS OF INTEREST

None reported.

WHAT IS KNOWN ABOUT THE TOPIC?

– Despite the experience gained with the technique and the miniaturization of the latest generation of transcatheter heart valves (currently using 14-Fr to 16-Fr sheaths), the transfemoral access is not feasible in about 15% to 20% of the patients.

– Regarding alternative access routes, fully percutaneous approaches (trans-subclavian/transaxillary, transcaval, and transcarotid) are preferred over surgical approaches (transaortic and transapical).

– To this date, no randomized clinical trials have ever been conducted comparing the different alternative percutaneous approaches.

– The use of alternative access routes depends on the center experience, the technique learning curve, and the patients' comorbidities and vascular anatomy.

WHAT DOES THIS STUDY ADD?

– The transfemoral rate of 5.4% registered in this analysis is far lower compared to the one described in the medical literature, which may reflect the recent developments and improvements in TAVI sheaths and increasing technical experience gained leading to a lower need for alternative access routes in the current clinical practice.

– In our cohort, trans-subclavian and transcaval TAVI showed higher 30-day and 1-year mortality rates in intermediate risk patients compared to what has been reported in the medical literature for other options such as surgical aortic valve replacements.

– In high-risk or inoperable patients with severe aortic stenosis ineligible for transfemoral TAVI, trans-subclavian and transcaval approaches proved feasible. However, procedural futility should be considered in these cases.

– Trans-subclavian and transcaval approaches did not show any differences regarding mortality, technical success, residual moderate-to-severe leak, major vascular complications, or in the 30-day rates of stroke, acute kidney injury, and major bleeding.

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Original article

Use of a pediatric risk score for cardiac catheterization in a Spanish population with congenital heart disease

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ABSTRACT

Introduction and objectives: Performing cardiac catheterization can be challenging regarding the management of congenital heart disease. Therefore, the use of risk scoring or grading systems can help us plan the procedure. Back in 2015, the Congenital Cardiac Interventional Study Consortium developed and validated a system called CRISP (Catheterization risk score for pediatrics), which predicted the risk of serious adverse events (SAEs) prior to cardiac catheterization. Our aim was to use and validate the same scoring system to predict SAEs associated with cardiac catheterization in a Spanish pediatric hospital.
Methods: A retrospective descriptive study was performed between January 2016 and May 2017. To create the area under the curve, the expected number of events was correlated with the overall number of cases (compared to the original CRISP). Pearson's chi-square test was used to assess the performance of the scoring system.
Results: A total of 516 patients were successfully enrolled, 26.6% of whom were < 1 year-old [range, 1 day to 18 years], 56.5% were males, and 17% weighed < 5 kg. Around 63.3% of the procedures performed were percutaneous compared to 1.2% that were hybrid. A total of 40 SAEs were found to be amenable to immediate correction with no associated mortality. CRISP showed good discrimination with an area under the curve of 0.71 (95%CI, - 0.66-0.91) compared to the original score of 0.74, and adequate goodness of fit with Pearson's chi-square test of 8.26 (*P* < .08).
Conclusions: Despite the performance of highly complex procedures, the rate of SAEs was similar to the one previously published. CRISP has proven to be a good benchmarking and risk stratification tool. Therefore, it can be successfully used in the Spanish pediatric population and have a positive impact on patient care like helping during pre- and post-catheterization care planning.

Aplicación de una puntuación de riesgo pediátrico para cateterismo cardiaco en una población española con cardiopatía congénita

RESUMEN

Introducción y objetivos: La realización de cateterismos cardiacos puede ser un reto en las cardiopatías congénitas, por lo que el uso de sistemas de puntuación o graduación del riesgo puede ayudar en la planificación del procedimiento. En 2015, el *Congenital Cardiac Interventional Study Consortium* desarrolló y validó un sistema llamado CRISP (*Catheterization Risk Score for Pediatrics*), que predecía el riesgo de eventos adversos graves previo a la realización del cateterismo cardiaco. Nuestro objetivo fue aplicar y validar el mismo sistema de puntuación para predecir eventos adversos graves relacionados con el cateterismo cardiaco en un hospital pediátrico español.
Métodos: Se realizó un estudio descriptivo retrospectivo desde enero de 2016 hasta mayo de 2017. Para obtener el área bajo la curva se correlacionó el número esperado de eventos con el número total de casos (comparados con el CRISP original). Se utilizó la prueba χ^2 de Pearson para evaluar el desempeño del sistema de puntuación.
Resultados: Se consiguió captar a 516 pacientes, de los cuales el 26,6% eran menores de 1 año (rango 1 día a 18 años), el 56,5% eran varones y el 17% tenían un peso inferior a 5 kg. En torno al 63,3% fueron intervenciones percutáneas y el 1,2% fueron procedimientos híbridos. Se constataron 40 eventos adversos graves susceptibles de corrección inmediata, sin mortalidad asociada. CRISP mostró una buena discriminación, con un área bajo la curva de 0,71 (IC95% −0,66 a 0,91), en contraste con la del sistema original de 0,74, y una adecuada bondad de ajuste, con test de Pearson de 8,26 (p < 0,08).

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Conclusiones: A pesar de la realización de procedimientos altamente complejos, los resultados en cuanto a eventos adversos graves fueron similares a los previamente publicados. CRISP ha demostrado ser una buena herramienta de evaluación comparativa y estratificación de riesgo, por lo que puede usarse con éxito en la población pediátrica española e impactar positivamente en la atención al paciente; por ejemplo, ayudando en la planificación de cuidados antes y después del cateterismo.

Palabras clave: Puntuación de riesgo. Cateterización cardiaca. Cardiopatía congénita. Población pediátrica.

Abbreviations

CCISC: Congenital Cardiac Interventional Study Consortium. **CHARM:** Congenital Heart Disease Adjustment for Risk Method. **CHD:** congenital heart disease. **CRISP:** Catheterization Risk Score for Pediatrics. **C3PO:** Congenital Cardiac Catheterization Project on Outcomes. **rCRISP:** refinement of CRISP.

INTRODUCTION

Before 2008, many attempts were made to create a standardized risk score to assess the likelihood of serious adverse events (SAEs) during pediatric cardiac catheterization. The field of pediatric cardiac catheterization has jointly designed and implemented several large, multicenter clinical registries including the Congenital Cardiac Interventional Study Consortium (CCISC) and the Congenital Cardiac Catheterization Project on Outcomes (C3PO).

The former registry started a project back in 2006 to define adverse events and risk adjustment.

This effort has yielded important information concerning the risk associated with the type of procedure being performed.[1,2] Back in 2015, the CCISC developed and validated an empirical preoperative catheterization risk score for pediatrics (CRISP). A 21-point scale that estimates the risk of procedural-related SAEs defined as any event leading to mortality, permanent morbidity, need for further procedures or extended lengths of stay. The CRISP derived from nearly 15 000 procedures added to the CCISC database from 27 centers of North and South America and a few European centers (eg, Evelina London Children's Hospital, London, United Kingdom).[3]

As this system has not been validated in most European countries—Spain included—we tried to use and validate the CRISP by assessing its predictive performance in 1 of the Spanish centers that runs pediatric cardiac catheterizations.

METHODS

The study was conducted after approval from our center Institutional Review Board and consent from the Research Ethics Committee to access patients' relevant health records including data storage and confidentiality. The participants' informed consent was not deemed necessary as it was a retrospective study handling anonymized data. We collected data retrospectively assessing all electronic and written health records available. We obtained information on all diagnostic and interventional catheterizations performed from January 2016 through May 2017. We excluded procedures with patients > 18 years-old, electrophysiological studies, transesophageal echocardiographies, vascular access, and pericardiocentesis.

Use of CRISP

We have translated the CRISP to Spanish without altering its original variables (note: although the tables may look different, the variables remain unchanged).

The patients' characteristics and type of procedure used were recorded as follows (= CRISP variables): age, weight, pre-catheterization diagnosis, systemic illness/organ failure, hemodynamic variables, inotropic support, procedural category, and case type (diagnostic, interventional, hybrid).[3]

Both the physiological parameters and anatomical diagnoses were defined based on the Society of Thoracic Surgeons/European Association for Cardio-thoracic Surgery shortlist. We divided them into 3 levels of perceived increased risk, procedural category, and case type. Multiple procedures were assigned to the highest-risk category.[1,3]

SAE was defined as any adverse event requiring further procedures, extended lengths of stay, causing permanent morbidity or eventual death.[3] The lead operator/investigator identified all SAEs and reviewed treatment modalities to apply severity definitions.

For practical purposes, Nykanen et al. suggested clustering the risk category into 5 different SAE risk groups: 1.0%, 2.6%, 6.2%, 14.4%, and 36.8%, respectively, rounded to the nearest whole percentage.[3]

The points assigned to each variable and the overall CRISP score were estimated and recorded in the database.

Statistical analysis

All data are expressed as percentages, mean, and median. SAEs were grouped according to severity as a percentage of the overall number of SAEs. These were estimated as the percentage of the overall number of procedures or population at risk for an event. All statistical analyses were performed using IBM SPSS Statistics statistical software platform, version 21.

To assess the performance of CRISP in our population, we created a receiver operating characteristic curve. To estimate its ability to predict SAEs, we applied Pearson's chi-square test ($P < .08$ were considered significant).[4]

RESULTS

From January 2016 through May 2017, a total of 669 patients we identified in our exploratory database. After applying exclusion criteria, 516 patients remained, 26.6% of whom were < 1 year-old [range, 1 day to 18 years-old], and 56.2% were males. The mean and median weights were 23.2 kg and 19.0 kg with 17% of the patients < 5 kg [range, 1.1 kg to 82.0 kg]. Procedures were diagnostic, interventional, hybrid or cardiac biopsies in 20.3%, 62.8%, 0.8%, and 16.1%, respectively (table 1).

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Table 1. Patient and procedural characteristics from January 1, 2016 through May 31, 2017

Variables	N (%)
Age	
< 1 months	32 (6.3%)
1 to 11 months	105 (20.3%)
< 1 years	**137 (26.6%)**
1-9 years	216 (41.8%)
10 to 18 years	165 (31.6%)
Male	290 (56.2%)
Female	226 (43.8%)
Weight	
< 2.49 kg	15 (2.9%)
2.5 to 4.9 kg	71 (13.8%)
< 5 Kg	**86 (16.7%)**
5 to 9 kg	72 (14%)
> 10 kg	358 (69.3%)
Diagnosis	
No structural heart disease[a]	130 (25.2%)
Pulmonary hypertension	11 (2.1%)
Isolated defects	169 (32.8%)
Complex defect with 2 ventricles	77 (14.9%)
Complex defect with 1 ventricle	121 (23.5%)
Noncardiac issues[b]	8 (1.5%)
Procedural characteristics	
Case type	
Diagnostic	105 (20.3%)
Interventional	324 (62.8%)
Hybrid	4 (0.8%)
Biopsy	83 (16.1%)

[a] Examples include patients with cardiomyopathy or post-heart transplantation.
[b] Including the snare technique foreign body removal procedure.

All catheterizations were performed under general anesthesia. During the period at stake, 3 operators performed the procedures, which gives robustness and homogeneity to our results.

A total of 23% of the population included patients with single-ventricle physiology while 14.9% had complex CHD with biventricular anatomy (eg, outflow tract obstruction and intra-cardiac shunts). A total of 32% had isolated injuries like atrial septal defect, patent ductus arteriosus or valvular abnormalities. In the overall cohort, 25.2% and 1.5% had non-structural heart diseases (eg, cardiomyopathy or heart transplant) and non-cardiac conditions (eg, retrieval of a foreign body), respectively.

Most procedures were categorized as category risk 3 and 5 (67.6%). These are the highest risk categories, which shows the complexity

Table 2. Rate of serious adverse events by proposed risk category

Risk category	Procedures (%)	Adverse events (%)	Expected adverse events (%)
CRISP 1	135 (26.2%)	3 (7.3%)	1 (1.0%)
CRISP 2	107 (20.7%)	5 (12.2%)	3 (2.6%)
CRISP 3	175 (33.9%)	15 (36.6%)	11 (6.2%)
CRISP 4	81 (15.7%)	14 (34.2%)	12 (14.4%)
CRISP 5	18 (3.5%)	4 (9.7%)	7 (36.8%)

CRISP, catheterization risk score for pediatrics.

of the procedures as risk categories increase. Our study area under the receiver operator curve (AUC) is 0.71, which is similar to the CRISP AUC of 0.74 (95% confidence interval (95%CI) of 0.66 to 0.91). No statistically significant differences were seen between the predicted risk and events obtained and Pearson chi-square test of 8.26 ($P < .08$).

Serious adverse events

A total of 40 SAEs (7.9%) were documented (description and frequencies shown are on table 2). First and foremost, of all the adverse events recorded, only 1 event per procedure was identified. No deaths or need for emergency surgery associated with cardiac catheterization were ever reported. Device embolization occurred in 6 patients; all were retrieved using percutaneous techniques. No device migration was reported after discharge. Arrhythmias requiring procedures were treated medically. Complete heart block was resolved with temporary pacemaker implantation.

Two cases of unexpected cardiac arrest requiring emergency extracorporeal membrane oxygenation support were reported. A non-syndromic 18-month child (CRISP category 4; risk of SAE, 14.4%) with a post-natal diagnosis of Shones syndrome (critical aortic stenosis and ventricular dysfunction). He underwent multiple procedures including aortic angioplasty, pulmonary bi-banding, and PDA stenting in the neonatal period followed by Ross–Konno procedure when he turned 9 months old. During catheterization, he showed electromechanical dissociation without response to cardiopulmonary resuscitation requiring extracorporeal membrane oxygenation. After stabilization, stenting was performed in both pulmonary arteries, left anterior descending, and left circumflex coronary arteries.

The other patient was a 10-year-old with suspected myocarditis in the context of an influenza A infection and cardiogenic shock (CRISP category 5; risk of SAE, 36.8%) who required inotropic support during cardiac catheterization. The procedure included an atrioseptoplasty with cardiac perforation and cardiac tamponade. He underwent 2-min cardiopulmonary resuscitation that needed extracorporeal membrane oxygenation support.

Not surprisingly, the rate of SAEs increased with higher risk scores (table 3). Two patients received 19 points, but no one a maximum score (21 points).

DISCUSSION

The original CRISP has already proven to be a robust risk predictor of SAEs.[4] Comparison with CCISC data was intentional trying to establish a benchmark. Therefore, it's not surprising to see that many features and outcomes are analogous.

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Table 3. Adverse events

SAE	Overall SAE, %
Hemodynamically unstable arrhythmia requiring pharmacological therapy	5 (12.2%)
Balloon rupture with no vascular damage or need to interrupt the procedure	2 (4.9%)
Unexpected cardiac arrest with emergency ECMO support	2 (4.9%)
Cardiac injury (mild left atrial posterior wall dissection)	2 (4.9%)
Complete heart block unresolved at the end of the procedure	1 (2.4%)
Deaths	0 (0.0%)
Device migration requiring removal via cut down or transcatheter retrieval	5 (12.2%)
Postoperative device migration	1 (2.4%)
Ductal dissection (wall hematoma without contrast extravasation)	1 (2.4%)
Hematoma requiring monitorization	4 (9.8%)
Hemodynamic instability with loss of pulse wave and impaired LV function	1 (2.4%)
Mild hypotension	1 (2.4%)
Mild vascular access dissection (no need to interrupt the procedure)	3 (4.9%)
TTE-related self-limited pulmonary bleeding	1 (2.4%)
Severe desaturation with bradycardia	1 (2.4%)
Severe hypotension with/or bradycardia	8 (17.1%)
Vasospasm	1 (2.4%)
Venous damage requiring transcatheter procedure	1 (2.4%)
	40 (7.7%)

ECMO, extracorporeal membrane oxygenation; SAE, serious adverse events; TTE, transthoracic echocardiogram.

A potential drawback of CRISP is the introduction of physiological variables like pulmonary vascular resistance, right ventricular systolic pressure, and anemia requiring intraoperative transfusion. Although these variables can sometimes be estimated non-invasively beforehand, they may not be reliable as their true quantification is unknown before cardiac catheterization. A recent refinement of CRISP (rCRISP) published back in 2018 excluded those 3 physiological markers. However, it performed well regarding risk prediction with an AUC of 0.70 and observed/expected SAE ratios from 0.71 to 1.18. However, the revised model demonstrated a worse overall fit compared to the original CRISP (based on lower Akaike's [AIC], Schwarz's [BIC] information criteria, and -2log likelihood ratio [N2LL]).[5]

In this study, we have validated the CRISP scoring system, revealing decent predictive accuracy for SAEs. Our results are equivalent to the original scoring system confirmed by the agreement measure AUC 0.74 and 0.71 (CRISP and our study, respectively) [95%CI, 0.66-0.91].

We identified all SAEs recorded, those liable to immediate correction, and those that resulted in an unexpectedly extended length of stay, and need for medical or interventional treatment (whether surgical or transcatheter).

Although our study was implemented retrospectively, we would like to highlight that the corresponding risk categories in cases requiring extracorporeal membrane oxygenation were 4 and 5, the 2 with the highest risk of adverse events. If CRISP were available, these outcomes would be rather predictable. Therefore, greater attention would be paid to the need for highly differentiated care. Obviously, in the cases indicated, the outcome was very favorable. Still, the utility of this tool is evident in the preparation and anticipation of all the necessary care in more complex and high-risk procedures.

The mortality definition associated with CHD catheterization still needs to be elucidated since assessing mortality is challenging in this field.[3] Although, in this study, mortality rate is 0% and minimal in other studies, it should be interpreted with caution.

Furthermore, physicians are understandably concerned with unfair comparisons of sensitive topics, eg, critical evaluation of unfavorable outcomes and events used for compensation and accreditation. Consequently, comparing centers or operators to identify the best practices can be facilitated, thus acknowledging that confidence intervals will be broader in low-volume centers.

Interestingly, if we compare the rate of adverse events by risk category/group, we'll be seeing more complications from groups 1 to 4. Surprisingly or not, that is not true for group 5. These findings could be due to the smaller volume of patients in this group and the heterogeneity of complexity regarding the procedures performed in such group.

Still, CRISP has an appropriate goodness of fit (Person's chi-square test of 8.26 ($P < .08$).

Knowing that extrapolations are informal, and unquantified arguments are limited by assumptions,[6] we still believe that CRISP can be extrapolated to all pediatric populations undergoing cardiac catheterization in Spain as our results are rather consistent with the original study.

As a matter of fact, these data show that CRISP positively impacts patient care as it can be used to plan procedures in advance. It helps prepare the required equipment, technical staff, need for special care after the catheterization like intensive care unit admission. It can also be used reliably for parent counseling before each procedure.[5]

Study limitations

In addition to the limitations inherent to retrospective studies, a substantial data limitation is the lack of systematic assessment of procedural success as in former studies. To this date, a standardized assessment of procedural success is lacking, but it will likely be the focus of future studies.[3]

For a more inclusive analysis, we disclosed all SAEs recorded, although adverse events are readily identified outcomes and perceived to have a meaningful impact on patient outcomes. However, without systematic auditing, there's still a potential for loss of adverse events, especially after patient discharge.

It can be argued that sample size is crucial for a more accurate outcome and less estimation error. However, more is only, sometimes, better in sample sizing since we can estimate size effect based on previously reported or preclinical studies. For future reference, in retrospective and observational studies, if the original study already proved to be a strong predictor, a smaller sample would be adequate to prove the same effect.[7]

We aim to conduct a prospective registry to refine the analysis and make this model more robust in our center. In conclusion, it would

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be interesting to join a nationwide Spanish registry as we believe data will be more representative of a multicentric approach and with prospective experience so we could overcome the limitations mentioned above.

CONCLUSIONS

The CRISP system is a relatively simple tool for risk assessment before catheterization in the CHD domain. Despite our study assessed the risk of stratification based on a single-center database, this model has proven accurate. Therefore, we are confident that this score could also be extrapolated to all pediatric populations in Spain. We strongly believe that this scoring system can become a handy tool for risk prediction, thus planning and preparing procedures in advance. In addition, it can be used for benchmarking. Our outcomes reveal that we perform highly complex procedures with similar results compared to those previously published. Finally, we suggest the use of CRISP before cardiac catheterization for procedural risk assessment planning.

FUNDING

ETHICAL CONSIDERATIONS

The study was conducted after approval from our center Institutional Review Board and consent from the Research Ethics Committee to access patients' relevant health records including data storage and confidentiality. The participants' informed consent was not deemed necessary as it was a retrospective study handling anonymized data. Authors did not differentiate the possible variables of sex and gender as per SAGER guidelines, because in the pediatric population, these differences are not so obvious, and the study was retrospective; thus patient details were already recorded in the Hospital system.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

We did not use artificial intelligence in this research.

AUTHORS' CONTRIBUTIONS

All authors reviewed all data analysis and the manuscript previous version, critically reviewed significant intellectual content, and approved the manuscript final version for publication. They've all made themselves accountable on all aspects of the study while making sure that questions associated with the accuracy or integrity of any part of the study are properly investigated and resolved.

CONFLICTS OF INTEREST

J.L. Zunzunegui Martínez is a proctor for PFM Medical and St. Jude Medical. The remaining authors declared no conflicts of interest whatsoever.

ACKNOWLEDGMENTS

WHAT IS KNOWN ABOUT THE TOPIC?

– Several reports suggested risk factors regarding adverse events associated with pediatric cardiac catheterizations. The C3PO study group started a project in the United States back in 2006 that has yielded important information concerning the risk associated with the type of procedure. Also, it developed the multivariate CHARM model for outcome risk adjustment. On the other hand, the CCISC group developed a pre-catheterization risk scoring system for individual pediatric patients undergoing cardiac catheterization procedures.

WHAT DOES THIS STUDY ADD?

– The catheterization risk scoring system for the pediatric population is a relatively simple model that has yet to be sampled and validated in many European countries. We tested and proved that this RISK score is valid in our subgroup and could be used, in the near future, in all Spanish pediatric populations undergoing cardiac catheterizations. This score can be a handy tool to predict risk before cardiac catheterization, which helps prepare pre- and postoperative care, thus positively impacting patient care.

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Effectiveness of the DyeVert Power XT system during percutaneous coronary interventions

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ABSTRACT

Introduction and objectives: Contrast-induced-acute kidney injury (CI-AKI) is a potential complication of angiographic procedures. The DyeVert Contrast Reduction system (Osprey Medical, United States) is a device to reduce the concentration of contrast medium (CM) in the kidneys by decreasing the amount of CM delivered to patients. Unlike manual systems, few data are available on the DyeVert Power XT system, which is used in conjunction with automated contrast injection. The main aim of our study was to evaluate its effectiveness during percutaneous coronary interventions (PCI).
Methods: Between 2020 and 2022, 101 patients who underwent PCI with the DyeVert Power XT system (case group) were enrolled to evaluate the amount of CM saved through the use of this device, as well as the rate, severity, and predictors of CI-AKI. Patients who underwent PCI without the use of the device (control group) were enrolled to create a matched group allowing assessment of differences in CM and the CI-AKI rate.
Results: In the case group, the amount of CM saved was 114 ± 42 mL, representing an average of 32% of the total CM. Fourteen patients (13.9%) developed CI-AKI. The only independent predictors of CI-AKI were hematocrit (OR, 0.86; 95%CI, 0.74-0.99; *P* = .04) and ejection fraction (OR, 0.88; 95%CI, 0.82-0.95; *P* = .001). As a result of diversion by the device, the amount of CM delivered was lower in the case group than in controls (252 vs 267 mL; *P* = .42), but this difference was nonsignificant. Equally, the reduction in CI-AKI (14.3% vs 16.3%) was nonsignificant.
Conclusions: Hematocrit and ejection fraction may be more important predictors of CI-AKI than the CM volume normally used during PCI in the general population. The net practical benefit of DyeVert Power XT was low.

Keywords: Acute kidney injury. Contrast media. Percutaneous coronary intervention. DyeVert.

Eficacia del sistema DyeVert Power XT en el intervencionismo coronario percutáneo

RESUMEN

Introducción y objetivos: La nefropatía inducida por contraste (NIC) es una potencial complicación de los procedimientos angiográficos. El sistema DyeVert Power (Osprey Medical, Estados Unidos) permite reducir la concentración renal del medio de contraste al disminuir la cantidad administrada a los pacientes. Al contrario que sobre los sistemas manuales, existen pocos datos disponibles sobre el sistema DyeVert, que se utiliza junto a la inyección automática de contraste. El objetivo principal de este estudio fue evaluar su eficacia en procedimientos de intervencionismo coronario percutáneo (ICP).
Métodos: Entre 2020 y 2022 se incluyó a 101 pacientes a quienes se realizó ICP utilizando el sistema DyeVert Power XT (grupo de casos) para evaluar la cantidad ahorrada de medio de contraste, así como la tasa, la gravedad y los predictores de NIC. Además, se seleccionó un grupo control de pacientes a los que se había realizado ICP sin utilizar el sistema DyeVert para comparar la cantidad de medio de contraste administrado y la tasa de NIC.
Resultados: En el grupo de casos se redujo la administración de medio de contraste en 114 ± 42 ml (una media del 32% del total). Desarrollaron NIC 14 pacientes (13,9%). Los predictores de NIC fueron el hematocrito (OR = 0,86; IC95%: 0,74-0,99; p = 0,04) y la fracción de eyección (OR = 0,88; IC95%: 0,82-0,95; p = 0,001). Como resultado de la utilización del sistema DyeVert, la cantidad administrada de medio de contraste fue menor, pero sin diferencias estadísticamente significativas (252 frente a 267 ml; p = 0,42). La tasa de NIC fue menor con el sistema DyeVert, pero sin alcanzar la significación estadística (14,3 frente a 16,3%; p = 1,0).
Conclusiones: El hematocrito y la fracción de eyección, más que la cantidad de contraste administrada, pueden ser predictores de NIC en los pacientes que reciben ICP. El beneficio del sistema DyeVert fue bajo.

Palabras clave: Insuficiencia renal aguda. Medios de contraste. Intervención coronaria percutánea. DyeVert.

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INTRODUCTION

Contrast induced-acute kidney injury (CI-AKI) is a dreaded complication after diagnostic and interventional angiographic procedures and is linked to increased morbidity and mortality. In a large recent meta-analysis, the pooled incidence of CI-AKI after coronary angiography was 12.8%, with 95% confidence interval (95%CI) 11.7%-13.9%, and the associated mortality was 20.2% (95%CI, 10.7%-29.7%).[1] Multiple risk factors have been identified: contrast medium volume (CMV), advanced age (> 75 years), diabetes, anemia, conditions associated with hypotension, and ejection fraction (EF) < 40%.[2,3] Many of these risk factors are included in the Mehran score,[2] which identifies 4 risk classes of contrast-induced nephropathy (CIN) after PCI: low (≤ 5 points), moderate (6-10 points), high (11-15 points), and very high (≥ 16 points). The Mehran score and the recent Mehran 2 score[4] assign 1 point for each 100 mL of CMV up to a dose of 299 mL. Because volume depletion increases the CM concentration in renal tubules, the main preprocedural measure to reduce the occurrence of CI-AKI is intravenous administration of normal saline before and after the procedure, because other solutions provide no benefits[5]; hydration should be started 12 hours before and continued for 24 hours after the procedure at 1 mL/kg/h or 0.5 mL/kg/h if EF < 35% or New York Heart Association (NYHA) class > 2.[6] Another means of decreasing CM concentration in the kidneys is the DyeVert Contrast Reduction system (Osprey Medical Inc, United States), which reduces the amount of CMV delivered to patients during angiographic procedures, with noninferior image quality as attested by independent reviewers.[7,8] The DyeVert, DyeVert Plus and DyeVert Plus EZ are used in conjunction with manual contrast injection, and the DyeVert Power XT is used with automated contrast injection; the latter system has been little studied. The main aim of our study was to evaluate the effectiveness of the DyeVert Power XT system in reducing CM delivery during PCI.

METHODS

Study population

This single center, observational study was performed in patients who underwent PCI between September 2020 and December 2022 with the DyeVert Power XT system (case group) and in patients who underwent PCI during a similar period without the use of the device (control group).

Inclusion criteria for both groups were as follows: chronic kidney disease (CKD) [estimated glomerular filtration rate (eGFR) < 60 mL/min/m^2] and/or need for a complex PCI with the likelihood of receiving a large amount of CM; previous coronary artery bypass graft (CABG); chronic total occlusion (CTO) (complete blockage of a coronary artery lasting at least 3 months); bifurcation; and left main and/or multivessel disease (at least 2 vessels involved).

The exclusion criterion for both groups was the presence of end-stage kidney failure on dialysis treatment. We collected laboratory, instrumental, clinical, and procedural variables in the case

and control groups. Definitions of all these variables are reported in table 1, table 2, table 3, and table 4. For the variables included in the Mehran score, we used the same descriptions as those used in the score. eGFR was calculated by the Modification of Diet in Renal Disease (MDRD) 4-variable equation, left ventricular EF by 2-dimensional echocardiography during hospitalization and before arrival in the catheterization laboratory, and the risk of any post-PCI CIN by the Mehran score. Bifurcation/left main treatment (with single/double stent) consisted of the proximal optimization technique (POT) with kissing balloon inflation and eventually re-POT in all cases. Total CMV represents the volume that would have been delivered if DyeVert had not been used, ie, the sum of CMV delivered to patients and the CMV saved by DyeVert. CM injection flow was 4 and 3 mL/sec for the left and right coronary artery, respectively.

Image quality was evaluated by operators during the procedures. When quality was inadequate, exclusion of the device from the CM line was allowed for the shortest possible time.

AKI was defined as a rise in the concentration of serum creatinine ≥ 0.3 mg/dL within 48 hours after CM administration from the baseline value obtained before CM injection; further measurements after 48 hours were collected in patients with worsening kidney function; for its prevention, all patients received hydration with sodium chloride 0.9% intravenous solution at a rate of 1 or 0.5 mL/kg/h, as appropriate. The severity of AKI was defined according to Kidney Disease Improving Global Outcome (KDIGO) stages.

The research reported was performed in accordance with recommendations for clinical investigation (Declaration of Helsinki of the World Medical Association, October 2013) and was approved by an ethics committee. We declare that relevant informed consent was obtained from all participants and is available.

Objectives

In the case group, we evaluated the following: *a)* the amount of CMV saved using DyeVert and image quality; *b)* the rate and severity of CI-AKI and the rate of in-hospital all-cause death; *c)* laboratory, instrumental, clinical, and procedural differences in the 2 subgroups defined on the basis of the incidence of AKI; and *d)* independent predictors of CI-AKI.

In the overall population of the case and control groups, we performed propensity score matching (PSM) to obtain a group of patients with a sufficiently good balance (matched group), in which we evaluated the following: *a)* differences in CMV, and *b)* rate and severity of CI-AKI.

Statistical analysis

Categorical variables are expressed as the number and percentage of patients. Continuous parametric data are reported as the mean

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± standard deviation and continuous nonparametric data as the median [lower and upper quartile]; for assessment of normality, the Kolmogorov test was used. Patients' categorical variables were compared using the chi-squared test (with Yates' correction for continuity in the case of variables with only 2 categories) or the Fisher exact test, as appropriate. The unpaired *t*-test was used for continuous parametric variables and the Mann-Whitney *U*-test for continuous nonparametric variables; the same tests were used in the matched group. On univariate analysis, significance was defined as $P < .05$. To establish the independent predictors of AKI, we performed multivariable logistic regression analysis. Variables were selected according to significance in the univariate analysis. The chosen method was stepwise backward regression with a maximum of 20 iterations. Multicollinearity was assessed with tolerance and variance inflation factor (VIF) values. Receiver operating characteristic (ROC) curves were used to establish the optimal cutoffs of independent predictors for the diagnosis of AKI. To perform PSM, the algorithm used was nearest neighbor matching 1:1 with a caliper size of ± 0.2. Statistical analyses were performed using SPSS for Windows, release 29, with R 4.2 implementation to perform PSM.

RESULTS

Analysis in the case group

A total of 101 patients (median age 74 [68-80] years, male sex 79.2%, CKD 72.3%) underwent PCI with the use of the DyeVert Power XT system.

In the overall population of the case group, mean hematocrit (HCT) was 38.6 ± 4.9 %, median EF was 50% [35%-55%], and mean Mehran score was 11 ± 5 points.

Congestive heart failure (CHF) was present in 37 patients (36.6%), Mehran CI-AKI very high-risk class was present in 17 patients (16.8%) and Mehran CI-AKI low-risk class was present in 24 patients (23.8%) (table 1).

We enrolled 20 patients (19.8%) with previous CABG, 12 (11.9%) with CTO, 34 (33.7%) with bifurcations, 25 (24.8%) with left main coronary artery disease, and 44 (43.6%) with multivessel disease. Delivered CM was 242 (189-300) mL, total CM was 355 ± 110 mL, and saved CM was 114 ± 42 mL, with an average of 32% of the total CMV (table 2). In almost all patients (n = 96, 95% of patients), image quality was adequate, while the device was excluded to make it adequate for the shortest possible time in 5 patients. Without these exclusions, saved CMV would have been slightly higher and with trivial changes with regard to the comparison with controls: 33% of the total, a value derived from patients without exclusions (n = 96).

A total of 14 (13.9%) patients developed CI-AKI (AKI-KDIGO 1, 2, 3: 6.9%, 3%, and 4%, respectively). The results of the univariate analysis for the overall population and according to the incidence of CI-AKI in the case group are reported in table 1, table 2, and figure 1.

Compared with patients not developing CI-AKI, those in the CI-AKI subgroup had lower HCT values (35.5 ± 4.8 vs 39.1 ± 4.8; $P = .01$), lower EF values (30 [28-36] vs 50 [40-55]; $P < .001$) and higher Mehran score values (15 ± 4 vs 10 ± 5; $P < .001$).

Table 1. Laboratory, instrumental, clinical characteristics, and Mehran score in the overall population and according to incidence of CI-AKI in the case group

Characteristics	Overall population (n = 101)	No CI-AKI (n = 87)	CI-AKI (n = 14)	P
Laboratory and istrumental characteristics				
eGFR, mL/min	51 ± 18	52 ± 19	45 ± 16	.18
HCT	38.6 ± 4.9	39.1 ± 4.8	35.5 ± 4.8	.01*
EF	50 [35-55]	50 [40-55]	30 [28-36]	< .001*
CKD [eGFR < 60 mL/min/ 1.73 m²]	73 (72.3)	63 (72.4)	10 (71.4)	1
Anemia [male HCT < 39%, female HCT < 36%]	48 (47.5)	38 (43.7)	10 (71.4)	.10
Clinical characteristics				
Age, years	74 (68-80)	73 (67-80)	75 (74-81)	.09
Age > 75 years	39 (38.6)	32 (36.8)	7 (50)	.52
Male sex	80 (79.2)	68 (78.2)	12 (85.7)	.73
Overweight [body mass index ≥ 25]	52 (51.5)	46 (52.9)	6 (42.9)	.68
Hypertension	78 (77.2)	70 (80.5)	8 (57.1)	.08
Diabetes	48 (47.5)	40 (46)	8 (57.1)	.62
Dyslipidemia	68 (67.3)	57 (66)	11 (79)	.51
Current smoker	24 (23.8)	20 (23)	4 (28.6)	.74
Former smoker	35 (34.7)	32 (36.8)	3 (21.4)	.37
CHF [NYHA class ≥ 3 and/or history of pulmonary edema]	37 (36.6)	25 (28.7)	12 (85.7)	< .001*
Acute coronary syndrome presentation	38 (37.6)	31 (35.6)	7 (50)	.46
Hypotension [Systolic arterial pressure < 80 mmHg for ≥ 1 h requiring inotrope]	4 (4)	2 (2.3)	2 (14.3)	.09
Mehran score				
Mehran CI-AKI risk class:				
Low	24 (23.8)	24 (27.6)	0 (0)	.04*
Moderate	26 (25.7)	24 (27.6)	2 (14.3)	.51
High	34 (33.7)	29 (33.3)	5 (35.7)	1
Very high	17 (16.8)	10 (11.5)	7 (50)	.002*
Mehran score, points	11 ± 5	10 ± 5	15 ± 4	< .001*

Values are expressed as No. (%), mean ± standard deviation, or median [first quartile-third quartile].
*Statistically significant *P*-value (*P* < .05).
CHF, congestive heart failure; CI-AKI, contrast induced-acute kidney injury; CKD, chronic kidney disease; EF, ejection fraction; eGFR, estimated glomerular filtration rate; HCT, hematocrit; NYHA, New York Heart Association.

In addition, the first patients more frequently had CHF [12 (85.7%) vs 25 (28.7%); $P < .001$] and Mehran CI-AKI very high-risk class (7 [50%] vs 10 [11.5%]; $P =.002$) and less frequently had Mehran CI-AKI low-risk class (0 [0%] vs 24 [27.6%]; $P = .04$).

Table 2. Procedural characteristics in the overall population and according to incidence of CI-AKI in the case group

Characteristics	Overall population (n = 101)	No CI-AKI (n = 87)	CI-AKI (n = 14)	P
Procedural characteristics (angiography/PCI complexity/complications)				
Previous CABG	20 (19.8)	18 (20.7)	2 (14.3)	.73
CTO [complete blockage of a coronary artery lasting at least 3 months]	12 (11.9)	11 (12.6)	1 (7.1)	1
No. vessels treated in the same procedure:				
1	57 (56.4)	52 (59.8)	5 (35.7)	.09
2	40 (39.6)	32 (36.8)	8 (57.1)	.15
3	4 (4)	3 (3.4)	1 (7.1)	.45
No. bifurcations treated in the same procedure:				
0	67 (66.3)	58 (66.7)	9 (64.3)	1
1	31 (30.7)	27 (31)	4 (28.6)	1
2	3 (3)	2 (2.3)	1 (7.1)	.36
Left main treatment	25 (24.8)	20 (23)	5 (35.7)	.33
Stent, number	2 [1-3]	2 [1-3]	2 [1-3]	.75
Stent lenght, mm	52 [31-88]	51 [30-91]	57 [36-73]	.95
Perforation	3 (3)	3 (3.4)	0 (0)	1
IABP use	1 (1)	0 (0)	1 (7.1)	.14
Rotablator use	3 (3)	1 (1.1)	2 (14.3)	.05
Procedural characteristics (others)				
Radial access	88 (87.1)	75 (86.2)	13 (92.9)	.69
Femoral access	27 (26.7)	21 (24.1)	6 (42.9)	.19
Operator				
L	52 (51.5)	47 (54)	5 (35.7)	.20
A	30 (29.7)	26 (29.9)	4 (28.6)	1
B	4 (4)	3 (3.4)	1 (7.1)	.46
V	13 (12.9)	10 (11.5)	3 (21.4)	.38
S	2 (1.9)	1 (1.1)	1 (7.1)	.26
Contrast medium type:				
Iomeprol 350	9 (8.9)	7 (8)	2 (14.3)	.61
Iohexol 350	13 (12.9)	11 (12.6)	2 (14.3)	1
Iodixanol 320	79 (78.2)	69 (79.3)	10 (71.4)	.50
Contrast medium dose delivered, mL	242 [189-300]	240 [188-306]	258 [195-277]	.95
Total contrast medium dose [delivered plus saved], mL	355 ± 110	354 ± 79	356 ± 106	.95
IVUS use	24 (23.8)	23 (26.4)	1 (7.1)	.18

Data are expressed as No. (%), mean ± standard deviation, or median [first quartile-third quartile].
CABG, coronary artery bypass graft; CI-AKI, contrast induced-acute kidney injury; CTO, chronic total occlusion; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound.
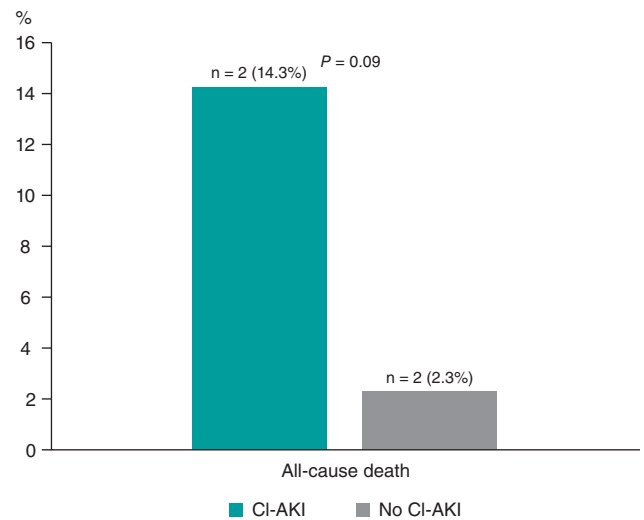
Figure 1. In-hospital all-cause mortality rate according to onset of CI-AKI in the case group. CI-AKI, contrast induced-acute kidney injury.
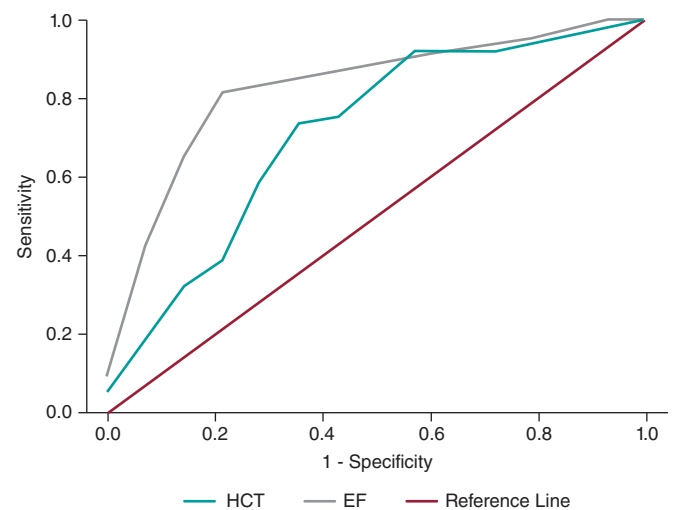
Figure 2. Receiver operating characteristic curves showing the diagnostic ability of HCT and EF for the diagnosis of CI-AKI in the case group. CI-AKI, contrast induced-acute kidney injury; EF, ejection fraction; HCT, hematocrit.

No significant differences were found in the remaining laboratory, instrumental, or clinical features or the procedural variables between the 2 subgroups; in particular, CM was slightly higher in CI-AKI patients: 258 [195-277] vs 240 [188-306] mL, total 356 ± 106 vs 354 ± 79 mL; P = .95 for both variables delivered. In the multivariate analyses, independent predictors of CI-AKI were HCT (OR, 0.86, 95%CI, 0.74-0.99; P = .04) and EF (OR, 0.88, 95%CI, 0.82-0.95; P = .001); the percentage accuracy in classification of the model was 88%, while tolerance and VIF values (0.99 and 1.01, respectively) showed no multicollinearity. The HCT ROC curve showed the following values: area under curve (AUC) 0.71 with 95%CI 0.56-0.87; P = .01; a cutoff of 36.3% had the best sensitivity (72%) and specificity (71%) for the outcome (figure 2). The EF ROC curve showed the following values: AUC 0.83 with 95%CI 0.72-0.94; P = .001; a cutoff of 37% had the best sensitivity (82%) and specificity (79%) (figure 2); therefore, our best predictor was EF < 40%.

There were 4 in-hospital all-cause deaths overall, 2 deaths in each subgroup (CI-AKI and no–CI-AKI subgroups), as shown in figure 1.

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Table 3. Laboratory, instrumental, clinical characteristics, and Mehran score of cases and controls in the matched group

Characteristics	No DyeVert (n = 49)	DyeVert (n = 49)	P	Standardized mean difference
Laboratory and istrumental characteristics				
eGFR, mL/min	53 ± 18	51 ± 18	.70	0.11
HCT	37.8 ± 4.1	38.2 ± 4.9	.68	0.08
EF	50 [40-55]	50 [35-55]	.68	0.13
CKD [eGFR < 60 mL/min/1.73 m²]	36 (73.5)	34 (69.4)	.82	0.09
Anemia [male HCT < 39, Female HCT < 36]	27 (55.1)	24 (49)	.69	0.12
Clinical characteristics				
Age, years	75 ± 9	75 ± 9	.96	0.01
Age > 75 years	26 (53.1)	24 (49)	.84	0.08
Male sex	38 (77.6)	41 (83.7)	.61	0.15
Overweight [body mass index ≥ 25]	22 (44.9)	24 (49)	.84	0.08
Hypertension	33 (67.3)	37 (75.5)	.50	0.19
Diabetes	19 (38.8)	20 (40.8)	1	0.04
Dyslipidemia	28 (57.1)	32 (65.3)	.53	0.17
Current smoker	11 (22.4)	10 (20.4)	1	0.05
Former smoker	16 (32.7)	18 (36.7)	.83	0.09
CHF [NYHA class ≥ 3 and/or history of pulmonary edema]	15 (30.6)	15 (30.6)	1	< 0.01
Acute coronary syndrome presentation	27 (55.1)	25 (51)	.84	0.08
Hypotension [systolic pressure < 80 mmHg for ≥ 1 h requiring inotrope]	2 (4.1)	2 (4.1)	1	< 0.01
Mehran score				
Mehran CI-AKI risk class:				
Low	12 (24.5)	10 (20.4)	.63	0.09
Moderate	12 (24.5)	15 (30.6)	.50	0.14
High	13 (26.5)	15 (30.6)	.65	0.09
Very high	12 (24.5)	9 (18.4)	.46	0.16
Mehran score, points	11 ± 6	11 ± 6	.86	0.04

Data are expressed as No. (%), mean ± standard deviation, or median [first quartile-third quartile].
CHF, congestive heart failure; CI-AKI, contrast induced-acute kidney injury; CKD, chronic kidney disease; EF, ejection fraction; eGFR, estimated glomerular filtration rate; HCT, hematocrit; NYHA, New York Heart Association.

Table 4. Procedural characteristics of cases and controls in the matched group

Characteristics	No DyeVert (n = 49)	DyeVert (n = 49)	P	Standardized mean difference
Procedural characteristics (angiography/PCI complexity/complications)				
Previous CABG	8 (16.3)	6 (12.2)	.56	0.10
CTO [complete blockage of a coronary artery lasting at least 3 months]	6 (12.2)	8 (16.3)	.77	0.13
No. vessels treated in the same procedure:				
1	32 (65.3)	29 (59.2)	.53	0.12
2	15 (30.6)	17 (34.7)	.67	0.08
3	2 (4.1)	3 (6.1)	1	0.10
No. bifurcations treated in the same procedure:				
0	33 (67.3)	31 (63.3)	.67	0.09
1	15 (30.6)	16 (32.7)	.83	0.04
2	1 (2.1)	2 (4)	1	0.12
Left main treatment	12 (24.5)	13 (26.5)	1	0.05
Stent, number	2 [1-3]	2 [1-3]	.30	0.15
Stent lenght, mm	46 [30-85]	52 [33-97]	.41	0.13
Perforation	2 (4.1)	1 (2)	1	0.12
IABP use	0 (0)	1 (2)	1	0.20
Rotablator use	0 (0)	2 (4.1)	.49	0.24
Procedural characteristics (others)				
Radial access	41 (83.7)	45 (91.8)	.35	0.24
Femoral access	11 (22.4)	15 (30.6)	.49	0.18
Operator:				
L	24 (49)	24 (49)	1	< 0.01
A	17 (34.7)	17 (34.7)	1	< 0.01
B	5 (10.2)	3 (6.1)	.71	0.20
V	3 (6.1)	5 (10.2)	.71	0.12
Contrast medium type:				
Iomeprol 350	7 (14.3)	4 (8.2)	.34	0.21
Iohexol 350	9 (18.4)	10 (20.4)	.80	0.06
Iodixanol 320	33 (67.3)	35 (71.4)	.66	0.10
IVUS use	10 (20.4)	11 (22.4)	1	0.05

Data are expressed as No. (%), mean ± standard deviation, or median [first quartile-third quartile].
CABG, coronary artery bypass graft; CI-AKI, contrast induced-acute kidney injury; CTO, chronic total occlusion; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound.

Analysis in the matched group

After the matching process, 49 patients remained in the control (no DyeVert) and case (DyeVert) groups with no significant imbalance (ie, standardized mean differences < ± 0.25), as reported in table 3 and table 4. As shown in figure 3, delivered CM was slightly lower in the DyeVert group than in the no-DyeVert group, with no significant difference (252 ± 80 vs 267 ± 101 mL; P = .42), while total CM was significantly higher in the DyeVert group (354 ± 110 vs 267 ± 101 mL; P < .001). The CI-AKI rate was slightly lower in the case
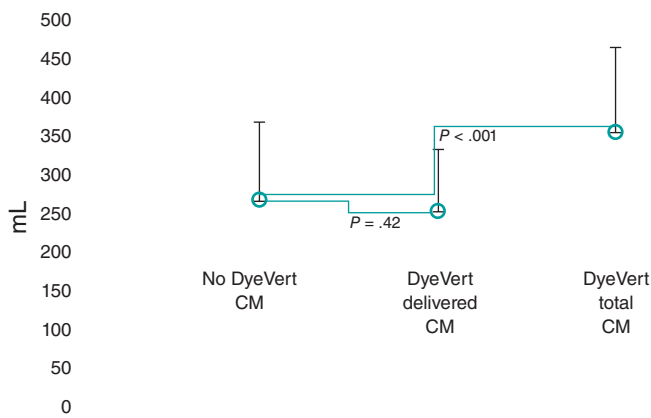
Figure 3. Contrast medium in cases and controls in the matched group. CM, contrast medium; blue dots represent the median values; vertical black lines represent the standard deviations.

group than in the control group (14.3% vs 16.3%; *P* = .99) with slightly more advanced stages of AKI in controls (table 1 of the supplementary data), without significance.

DISCUSSION

In the case group, the DyeVert Power XT system saved 32% of CM and image quality was adequate in almost all cases; the only independent predictors of CI-AKI were HCT and EF.

In the matched group, total CM was higher in cases than in controls. After diversion by the device, delivered CM was slightly lower in cases than in controls, but without significance. The reduction in CI-AKI was also nonsignificant.

The DyeVert system is a second-generation device to reduce the amount of CM delivered to patients during angiographic procedures. The first generation was the AVERT system (Osprey Medical Inc), which showed a relative reduction of approximately 23% in CMV among PCI patients compared with controls; the use of the device did not reduce the AKI rate.[9] DyeVert Power XT is used in combination with automatic injection; few data are available in this context, being limited to 2 studies that investigated 26[10] and 9 patients,[11] without a control group. There are more data on manual injection (1696 patients, 15 studies); all these 17 studies were collectively analyzed in the meta-analysis by Tarantini et al.[12]

In that meta-analysis, the mean saved CMV in the DyeVert group was reported by 7 observational studies and ranged from 34% to 47% of total CMV; the pooled estimate value was approximately 39.5% using manual CM injection systems; of note, the lowest value (34%) was achieved using DyeVert Power XT. We found a similar value in the DyeVert (case) group. These reduced values compared with manual systems may be related to different pressures generated during automatic contrast injection.

In our case group analysis, CMV was not significantly correlated with the occurrence of CI-AKI, which instead was independently predicted by lower HCT and EF values, which are known risk factors, as shown by Mehran scores.[2,4] EF was also an independent predictor in the study by Briguori et al.[13] Our findings confirm the importance of first identifying the variables (eg, those in the Mehran or Mehran 2 scores)[2,4] that classify patients at higher risk of CI-AKI

to apply appropriate preventive strategies. In the present study, these patients were identified by HCT and EF and consequently the latter variables (especially EF) may be more important predictors than CMV, which is normally used during PCI in the general population. In the above-mentioned scores, CMV was also an independent predictor of CI-AKI and, consequently, using the smallest possible value of CMV is still important, especially in higher risk patients. DyeVert thus has the potential benefit of reducing CIN, depending on its efficacy compared with controls, which was evaluated in the above-mentioned meta-analysis and in the present study.

In the meta-analysis, approximately half of the studies included controls for comparison. Delivered CM was usually lower in DyeVert patients than in controls. In these cases, the difference ranged from 22 to 50 mL,[12] with the highest differences being reported in the studies by Tajti et al. (200 [153-256] vs 250 [170-303] mL; *P* = .04) and Briguori et al. (99 ± 50 vs 130 ± 50 mL; *P* < .001).[13,14] Delivered CMV was slightly higher (difference of 2 mL) in the DyeVert group only in the study by Bunney et al.[15] The pooled analysis showed a significant decrease in delivered CMV with DyeVert use relative to the control group. Of note, details about prior CABG, CTO and left main treatment were reported only in 1 work[14] and the number of vessels treated was reported only in another work.[13] The treatment of bifurcations and differences in operators were not reported. All these procedural characteristics, which may influence the amount of CM delivered during PCI, were included in our study and we used a matched group with a sufficiently good balance in the studied characteristics.

In our matched group, delivered CM was lower in the case group than in the control group, but the difference was slight and nonsignificant, while total CM (also called *attempted* in the meta-analysis) was significantly higher in the case group than in the control group. Consequently, the net practical benefit of the device in terms of spared CM was low. In our work, procedural characteristics (eg, procedural complexity), which could cause discrepancies in CM injections, were balanced in the matched group. Based on these findings, we believe that the control group required more prolonged and/or a greater number of contrast injections (and consequently more total CM) to achieve adequate image quality. In previous studies, adequate image quality was achieved with DyeVert in 98% of cases,[12] a value similar to ours, but those studies did not discuss the need for prolonged injections and more total CM compared with controls to maintain image quality when DyeVert is used. Few data are available on total CM, but previous studies reporting this information indicate that total CM was higher in DyeVert patients than in controls (Briguori et al., *P*-value almost significant; Kutschman et al., *P*-value not reported).[12,13,16]

The reduction in CI-AKI in the present study was not statistically significant. In the meta-analysis, the pooled relative risk for CI-AKI associated with DyeVert system use was 0.60 (95%CI, 0.40-0.90; *P* = .01), which was a result derived from 5 studies. Moreover, in a recent abstract not included in the meta-analysis, postprocedure eGFR values among patients undergoing coronary and/or peripheral angiography were significantly more stable in the DyeVert group than in controls.[17]

Analysis of the 5 above-mentioned studies separately revealed that our results are mainly in agreement; indeed, the relative risk was significantly lower in only 1 study in the nonpooled analysis.[13]

The type of CM was not associated with the occurrence of CI-AKI; as recommended,[18] we used iso-osmolar (Iodixanol 320) or low-osmolar

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(Iomeprol 350 or Iohexol 350) contrast agents to prevent CIN. Given the presence of more favorable evidence,[19] we preferred to use the iso-osmolar agent and reserved the other agents to low-risk patients.

Study limitations

Our study has some limitations. First, the sample size was relatively small. Second, the study design was single center, observational and retrospective, although we performed PSM to reduce potential confounding bias. Third, we excluded patients not meeting the inclusion criteria, as they were usually at low risk of CI-AKI. Therefore, our results should be generalized with caution, since the analyzed patients may be not representative of the general population. In this work the variable of sex has not been taken into account in accordance with the SAGER guidelines.

CONCLUSIONS

The DyeVert Power XT system saved 32% of CM, but only HCT and EF were independent predictors of CI-AKI and the main predictor was EF < 40%. Therefore, these variables (especially EF) may be more important than CMV, which is normally used during PCI in the general population.

PCI with this system required more total CM compared with that in controls to achieve adequate image quality. Consequently, after CM saving by the device, delivered CM was only slightly lower than CM in controls (mean difference of 15 mL) and this difference was nonsignificant. Therefore, the net practical benefit of the system was low. Equally, the reduction in CI-AKI (14.3% vs 16.3%) was not statistically significant.

Future studies are needed to confirm these results.

FUNDING

The authors did not receive any grants for this research.

ETHICAL CONSIDERATIONS

The work has been approved by an Ethics Committee/institution. Informed consent of patients was obtained and archived for the publication of their cases. In this work the variable of sex has not been taken into account in accordance with the SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

We didn't use artificial intelligence for the development of our work.

AUTHORS' CONTRIBUTIONS

F. Vergni, M.Arioti, and M.Leoncini contributed to the design of the work. F. Vergni, M. Arioti, V. Boasi, F.A. Sánchez, M.Leoncini, and F. Ferrari contributed to the acquisition of data. F. Vergni analyzed the data. F. Vergni, M.Arioti, V. Boasi, F.A. Sánchez, M. Leoncini, and F. Ferrari contributed to the interpretation of the data. F. Vergni and M.Arioti contributed to the drafting of the work. F. Vergni, M. Arioti, V. Boasi, F.A. Sánchez, M.Leoncini, and F. Ferrari revised the work and approved the final version to be published.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

WHAT IS KNOWN ABOUT THE TOPIC?

– The DyeVert Power XT system (which is used in conjunction with automated contrast injection) has been assessed in only 2 studies, which included a total of 35 patients investigated without a control group and mainly not during PCI.

WHAT DOES THIS STUDY ADD?

– Our study investigated the device in a larger population (n = 101) and during PCI. Moreover, we included a control group and performed propensity score matching to obtain a group of patients with a sufficiently good balance regarding laboratory, instrumental, clinical and procedural characteristics; in addition, among the latter features, we included the treatment of coronary bifurcations and differences between operators, which were not reported in previous studies. The above-mentioned characteristics may influence the outcome (ie, CI-AKI occurrence) and/or the volume of CM used and therefore their inclusion is important when assessing a device to spare CM.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000409.

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Excimer laser coronary atherectomy in severely calcified lesions: time to bust the myth

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ABSTRACT

Introduction and objectives: No previous studies have established the contemporary use and outcomes of Excimer laser coronary atherectomy (ELCA) in percutaneous coronary intervention (PCI) of severely calcified coronary lesions. The aim of this study was to assess the safety, efficacy, and 1-year outcomes of ELCA in this setting.
Methods: We retrospectively examined the clinical and angiographic characteristics and procedural outcomes of severely calcified lesions treated with ELCA-assisted PCI in our institution between 2016 and 2022.
Results: Seventy-eight consecutive patients (80 procedures) were included (mean age 71.2 ± 8.6 years, 80.5% men). Clinical presentation was stable coronary artery disease in 45 patients (56.2%) and acute coronary syndromes in 33 (43.8%). All the lesions were severely calcified. In addition, 40% were uncrossable lesions, 28.75% were undilatable lesions, 2.5% showed in-stent restenosis, 6.25% showed stent underexpansion, and 7.5% were chronic total occlusions. The combination of ≥ 2 of the above anatomic settings was found in 12.5% of the procedures. The maximum fluence was 73 ± 9.6 mJ/mm², and the maximum frequency was 72.7 ± 10.4 Hz. The saline flushing technique was initially used in all the procedures, while contrast was used in 2 procedures. The ELCA success and technical success rates were both 91.25%. Adjuvant plaque modification therapies were required in 4 patients. The clinical success rate was 87.5%. ELCA-related complications occurred in 2 procedures (2.5%). After a median follow-up of 15.5 months [IQR, 5.0-29.3], major adverse cardiac events (MACE) (target lesion revascularization, myocardial infarction or cardiac death) occurred in 9 patients (11.25%).
Conclusions: Despite the complexity of PCI in severely calcified lesions, ELCA was effective with a relatively low incidence of ELCA-related complications and MACE during follow-up.

Keywords: Complex PCI. Excimer laser coronary atherectomy. Calcified coronary lesions.

Láser Excimer en lesiones coronarias gravemente calcificadas: tiempo de romper el mito

RESUMEN

Introducción y objetivos: El uso contemporáneo y los resultados de la aterectomía coronaria con láser Excímer (ELCA) en el intervencionismo coronario percutáneo (ICP) de lesiones coronarias gravemente calcificadas no están establecidos. El objetivo de este estudio fue evaluar la eficacia, seguridad y resultados a 1 año de ELCA en este escenario.
Métodos: Se revisaron de forma retrospectiva las características clínicas y angiográficas, y los resultados de los procedimientos de revascularización de lesiones gravemente calcificadas tratadas con ICP asistido por ELCA en nuestro centro entre 2016 y 2022.
Resultados: Se incluyeron 78 pacientes consecutivos (80 procedimientos) (edad media 71,2 ± 8,6 años, 80,5% varones). La presentación clínica fue enfermedad arterial coronaria estable en 45 (56,2%) pacientes y síndromes coronarios agudos en 33 (43,8%). Todas las lesiones presentaban calcificación grave. Además, el 40% eran lesiones incruzables, el 28,75% lesiones indilatables, el 2,5% reestenosis intra*stent*, el 6,25% infraexpansión del *stent* y el 7,5% oclusiones crónicas. La combinación de ≥ 2 de los escenarios anatómicos anteriores existió en el 12,5% de los procedimientos. La fluencia máxima fue de 73 ± 9,6 mJ/mm² y la frecuencia máxima de 72,7 ± 10,4 Hz. ELCA con lavado con solución salina se utilizó inicialmente en todos los procedimientos y se utilizó contraste en 2 procedimientos. La tasa de éxito de ELCA y de éxito técnico fueron del 91,25 %. Fueron necesarias terapias adyuvantes de modificación de placa en 4 casos. La tasa de éxito clínico fue del 87,5%. Ocurrieron complicaciones relacionadas

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con ELCA en 2 (2,5%) procedimientos. Tras una mediana de seguimiento de 15,5 meses (IQR, 5,0-29,3), se produjeron eventos cardiovasculares adversos mayores (MACE) (nueva revascularización de la lesión diana, infarto de miocardio o muerte cardiaca) en 9 pacientes (11,25%).

Conclusiones: A pesar de la complejidad de la ICP en lesiones gravemente calcificadas, ELCA demostró ser efectivo con una incidencia relativamente baja de complicaciones relacionadas con ELCA y MACE en el seguimiento.

Palabras clave: ICP compleja. Láser coronario. Lesiones coronarias calcificadas.

Abbreviations

CTO: chronic total occlusion. **ELCA:** excimer laser coronary atherectomy. **ISR:** in-stent restenosis. **MACE:** major adverse cardiovascular events. **PCI:** percutaneous coronary intervention. **RA:** rotational atherectomy.

INTRODUCTION

Moderate or severe coronary artery calcification is relatively common in patients undergoing percutaneous coronary interventions (PCI).[1] This is closely related to advancing age and the high prevalence of comorbidities such as diabetes or chronic kidney disease. Coronary artery calcification is associated with a lower rate of successful PCI and complete revascularization, increased procedural-related complications, and a higher rate of major adverse cardiovascular events (MACE).[2]

Despite the availability of several plaque modification techniques, severely calcified lesions continue to pose a challenge to the successful performance of PCI.

Excimer laser coronary atherectomy (ELCA) is a plaque modification technique that has proved to be useful in various scenarios such as balloon failure (uncrossable or undilatable lesions), chronic total occlusions (CTO), stent underexpansion, in-stent restenosis (ISR), and thrombotic lesions. In recent years, incremental operator experience along with the standardization of the laser technique, has expanded its indications and decreased its complication rates.[3,4]

However, its effectiveness in calcified lesions is controversial. On one hand, some ELCA series have described a relationship between severe calcification and laser failure.[5-8] On the other hand, moderate-to-severe calcification is found in more than 60% of cases in some ELCA series with a high success rate,[9] suggesting that it could be useful in this setting.[10]

Due to the lack of evidence in this specific scenario, the aim of our study was to assess the safety and efficacy of ELCA in severely calcified coronary lesions, as well as the mid-term follow-up outcomes in a single center registry.

METHODS

Patient population

This single center retrospective observational study included all consecutive patients undergoing ELCA-assisted PCI for severely calcified lesions. From March 2016 to August 2022.

We excluded procedures using ELCA for any indication other than severe calcification. In all patients, PCI was indicated based on the presence of symptoms consistent with angina, demonstrated ischemia, or both. The study followed the international recommendations

of clinical investigation (Declaration of Helsinki). All participants gave written informed consent and approval was obtained from the ethics committee of the center. The study took into consideration sex and gender variables according to SAGER guidelines. Patients were followed up in cardiology clinics at their referral center 3 to 6 months after the procedure, and thereafter at time intervals established at the discretion of their treating physician.

We analyzed data on clinical and angiographic characteristics, technical aspects of the procedure, and cardiovascular events during hospitalization and after discharge.

Procedure

All procedures were carried out by 5 different operators experienced in the use of ELCA. The decision to use ELCA was based on the presence of angiographically severe calcification.

Radial access was use by default. All cases were performed with the CVX-300 Excimer Laser System (Philips, Netherlands) using the 0.9 mm or 1.4 mm catheters. Saline infusion technique was used by default from the beginning, with fluence (mJ/mm^2), frequency or repetition rate (Hertz), and the possibility to use ELCA without saline infusion or even with contrast left to the operator's discretion. Additional dilatation with noncompliant balloons was performed in all procedures. Patients in which another plaque modification technique was used in combination with ELCA were included. All PCIs were performed following current recommendations.[11]

Definitions

Severely calcified lesions were angiographically defined as radiopacities observed on fluoroscopy without cardiac motion before contrast injection compromising 1 or both sides of the lumen.[12] Balloon-uncrossable lesions were defined as lesions that could not be crossed with the lowest-profile balloon available or a microcatheter despite successful advancement of the guidewire distal to the lesion, having good guide catheter support with a guide extension catheter when required. Balloon-undilatable lesions were defined as those lesions in which a noncompliant balloon (diameter 1:1 according to the vessel diameter) failed to achieve adequate expansion. Anterograde flow was assessed by the Thrombolysis In Myocardial Infarction (TIMI) scale.

ELCA success was defined as the ability to cross the lesion completely with the laser catheter or, if crossing was not feasible, to allow the subsequent passage and expansion of a balloon sized

1:1 with the vessel diameter, after laser application. Technical success was defined as residual stenosis < 30% and anterograde TIMI 3 flow in the target vessel. Clinical success was defined as technical success and the absence of MACE during the current hospitalization (target lesion revascularization, procedure-related myocardial infarction [MI], or cardiovascular death). Procedural-related complications included coronary artery perforation leading to cardiac tamponade and requiring pericardial drainage, flow-limiting dissection, no-reflow, hemodynamic instability, MI type 4a according to the fourth universal definition of MI,[13] ventricular arrhythmias, and major bleeding (bleeding requiring transfusion and/or surgical or percutaneous intervention). MACE occurring during follow-up were defined as a composite of target lesion revascularization, MI, or cardiac death.

Statistical analysis and data collection

All data were collected through the patients' electronic medical records and were introduced in a local database. Angiograms were evaluated using local quantitative coronary analysis software and visual operators' assessment. Categorical variables are reported as absolute values and percentages. Continuous variables are presented as the mean ± standard deviation (SD) or median (interquartile range [IQR] 25-75), depending on their normal or nonnormal distribution. All analyses were performed with StatIC 16.1 statistical software package.

RESULTS

Clinical characteristics

During the study period, a total of 78 patients with severely calcified coronary lesions underwent 80 ELCA-assisted PCIs and were included in the analysis. Patients undergoing ELCA for an indication other than severe calcification were excluded from the analysis. The distribution of the number of procedures per year, between March 2016 and May 2022, is shown in figure 1. A flowchart of patients in the present study is summarized in figure 2. Mean age was 71.2 ± 8.6 years, 62 (80.5%) were men, and there was a high prevalence of cardiovascular risk factors. Mean left ventricle ejection fraction was 52.9% ± 12.5%. Thirty-nine patients (50%) had a previous PCI. Clinical presentation was stable coronary artery disease in 45 procedures (56.2%), non–ST-segment elevation MI (NSTEMI) in 28 (35%), and ST-segment elevation MI (STEMI) in 7 (8.8%). Baseline clinical characteristics are summarized in table 1.

Angiographic characteristics

Severe multivessel disease was present in 56 patients (71.8%). The most common target vessel was the left anterior descending artery (38.75%). In 7 procedures (8.75%), more than 1 target vessel were identified. The anatomical settings in the target vessel included uncrossable lesions in 32 (40%), undilatable lesions in 23 (28.75%), ISR in 2 (2.5%), and stent underexpansion related to calcified plaque in 5 (6.25%). In 6 (7.5%) procedures, the main indication for ELCA was CTO combined with any of the previous settings. In 10 procedures (12.5%), the indication for ELCA resulted from the combination of 2 or more of the above. ELCA was used with the sole indication of severely calcified lesion, not included in any of the previous anatomical settings, in 2 procedures (2.5%).

Procedural characteristics

The radial approach was performed in 44 (55%) cases. There was no need for access conversion when the radial approach was attempted.
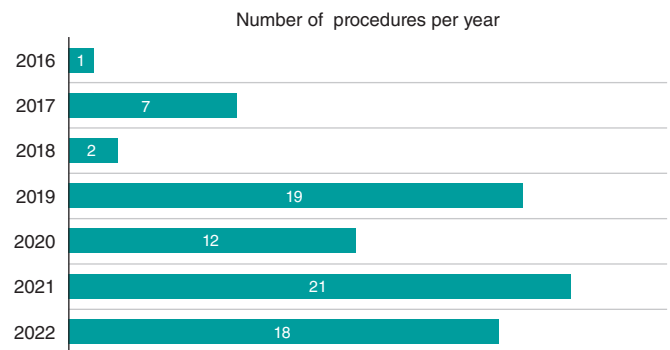
Number of procedures per year

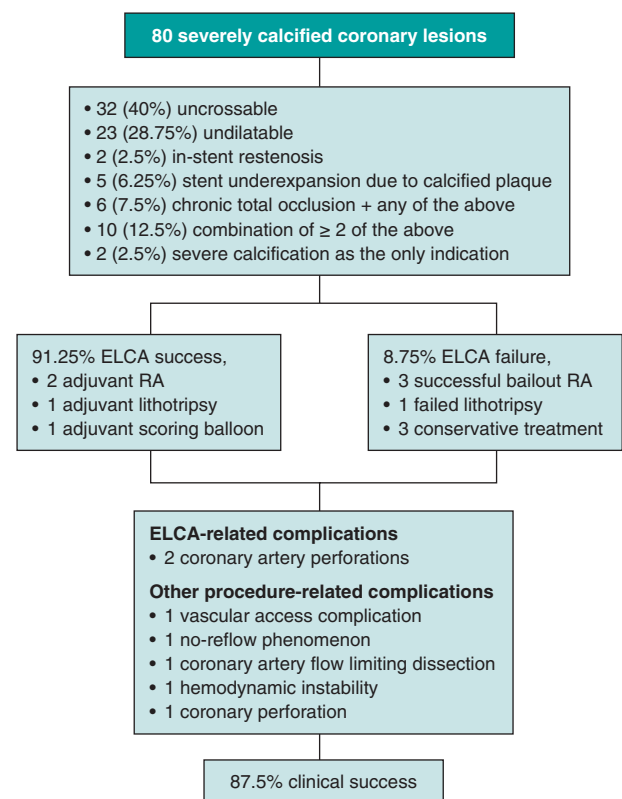**Figure 1.** Distribution of the number of procedures per year (March 2016-May 2022).

Figure 2. Flowchart of patients in the present study. ELCA, excimer laser coronary atherectomy; PCI, percutaneous coronary intervention; RA, rotational atherectomy.

Dual antiplatelet treatment consisted of pretreatment with aspirin and oral $P2Y_{12}$ receptor blockers in 58 patients (72.5%). Selection of $P2Y_{12}$ inhibitor was left to the physician's discretion. Cangrelor was used in the patients without prior dual antiplatelet treatment. After the procedure and during follow-up, dual antiplatelet treatment was prescribed as follows: in stable coronary artery disease (n = 45) clopidogrel was used in 21 patients, ticagrelor in 10 and prasugrel in 3 patients. In acute settings (n = 35), ticagrelor was administered in 16 patients, prasugrel in 10, and clopidogrel in 7. GPIIB/IIIA inhibitors were used in 6 procedures (7.5%) (tirofiban in all cases).

Intracoronary imaging was used in 58 procedures (72.5%). Optical coherence tomography (OCT) was used in 48 procedures (60%) and intravascular ultrasound in 10 (12.5%).

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Table 1. Baseline clinical characteristics

Age	71.2 ± 8.6
Male sex	62 (80.5%)
Body mass index (kg/m²)	28.7 ± 4.2
Hypertension	70 (89.7%)
Dyslipidemia	61 (78.2%)
Diabetes mellitus	46 (59.0%)
Current smoker	19 (24.4%)
Prior PCI	39 (50.0%)
Prior CABG	8 (10.3%)
Hb (g/dL)	13.5 ± 5.3
Serum creatinine (mg/dL)	1.42 ± 1.8
Ejection fraction (%)	52.9% ± 12.5
Clinical presentation (n = 98)	
Stable coronary artery disease	45 (56.2%)
NSTEMI	28 (35.0%)
STEMI	7 (8.8%)

CABG, coronary artery bypass graft surgery; NSTEMI, non–ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction. Data are expressed as no. (%) or mean ± standard deviation.

Circulatory support with intra-aortic balloon counterpulsation was required in only 1 patient in the context of left-main revascularization.

Regarding the ELCA technique, most lesions were treated with 0.9 mm laser catheters (97.5%). In 2 patients, larger catheters (1.4 mm) were used (1 case of ISR in the left anterior descending artery and 1 calcified lesion in a saphenous vein graft). Flushing saline was used in all the procedures, and contrast was required in 2 procedures (figure 3). Maximum fluence was 73 ± 9.6 mJ/mm² and the maximum frequency 72.7 ± 10.4 Hz. The highest fluence of 80 mJ/mm² was required in 48 (60%) procedures and the highest frequency of 80 Hz in 48 (60%). A mean of 5103 ± 3120 pulses was delivered, and the median lasing time was 62 seconds [IQR 40-91].

At least 1 new-generation drug-eluting stent was implanted in 70 procedures (87.5%). In the remaining procedures, stents were not delivered because of the presence of previous stents (6 ISR and 2 cases of stent underexpansion), which were treated with noncompliant and/or drug-eluting balloons, or due to ELCA failure (2 cases).

Angiographic and procedural characteristics and procedural strategy data are summarized in table 2.

Procedural outcomes

The ELCA success rate was 91.25%. The success rate was 78.1% in uncrossable lesions and 100% in the other anatomical settings (*P* < .001). The ELCA success rate in the different anatomical settings is shown in figure 4.

Among intracoronary imaging-guided procedures, the ELCA success rate was 98.3%, and dropped to 72.7% in non-coronary imaging-guided PCI (*P* < .001). Final stent expansion was analyzed with

intracoronary imaging in 32 procedures. The median stent expansion was 80.3% [IQR, 68.2%-95.2%].

Despite ELCA success, adjuvant plaque modification therapies (other than noncompliant [NC] balloon inflation after ELCA) were used in 4 procedures, including rotational atherectomy (RA) in 2 procedures, lithotripsy in 1 procedure and scoring balloon in 1 procedure. The procedures in which ELCA allowed subsequent successful RA (RASER technique[14]) or successful lithotripsy (ELCA-tripsy technique[15]) were considered ELCA success.

In 7 procedures (8.75%), ELCA failed. In 2 of them, RA was successfully performed. In 1 procedure, intravascular lithotripsy was attempted, but failed. In 1 case, the procedure was prematurely interrupted at the request of the patient. In the remaining 2 patients, no bailout therapy was attempted, and they were managed conservatively. Cases in which ELCA did not facilitate the passage of RA or intravascular lithotripsy were not classified as RASER or ELCA-tripsy techniques. The overall technical success rate was 91.25%.

In-hospital and follow-up outcomes

ELCA-related complications occurred in 2 procedures (2.5%) due to coronary artery perforation after ELCA application, with immediate sealing after stent implantation (although pericardiocentesis was necessary in 2 of them). A third perforation was observed, not immediately after ELCA application, but after dilatation with NC balloons. In 2 of the perforations, the target lesion was a severely calcified and undilatable lesion located in the left anterior descending artery. The third perforation was observed in an uncrossable lesion at the right coronary artery. In all of them, the 0.9 mm catheter was used, and ELCA was applied with maximum fluency and repetition rate during saline infusion. Intracoronary imaging prior to ELCA application was not performed in any of these patients: the OCT catheter could not cross the lesion in 2 of them and crossing was not attempted in the third. After the application of coronary laser and stent implantation, OCT was performed in 2 of the procedures, which confirmed the good final result.

Other procedural complications not related to ELCA occurred in 4 patients. One patient developed a vascular access complication with retroperitoneal hemorrhage and severe bleeding requiring transfusion and transarterial embolization of a deep femoral artery branch, although his clinical course was favorable. One patient with severe aortic stenosis and impaired left ventricular function showed hemodynamic instability requiring support with inotropes and orotracheal intubation. In 1 patient, no-reflow phenomenon occurred after stent implantation but resolved after intracoronary adenosine infusion.

In the remaining patient, coronary dissection occurred during the guidewire advancement before ELCA application and was complicated with occlusive intracoronary hematoma, which resolved after emergent PCI with successful revascularization. No patient died during the procedure. Three patients died during admission despite successful revascularization due to cardiac causes not related to the procedure (mostly advanced heart failure) and 1 patient died from respiratory sepsis. There were no other in-hospital complications. Overall, the clinical success rate was 87.5%.

After a median follow-up of 15.5 months [IQR, 5.02-29.3], MACE occurred in 9 patients (11.25%). Target lesion revascularization occurred in 7 patients (8.9%), in all patients due to ISR. The median time to target lesion revascularization among patients with successful revascularization was 11.4 [IQR, 8.1-22.6] months. Cardiorespiratory arrest secondary to acute stent thrombosis occurred in 1 patient with successful revascularization, whose family reported poor antiplatelet
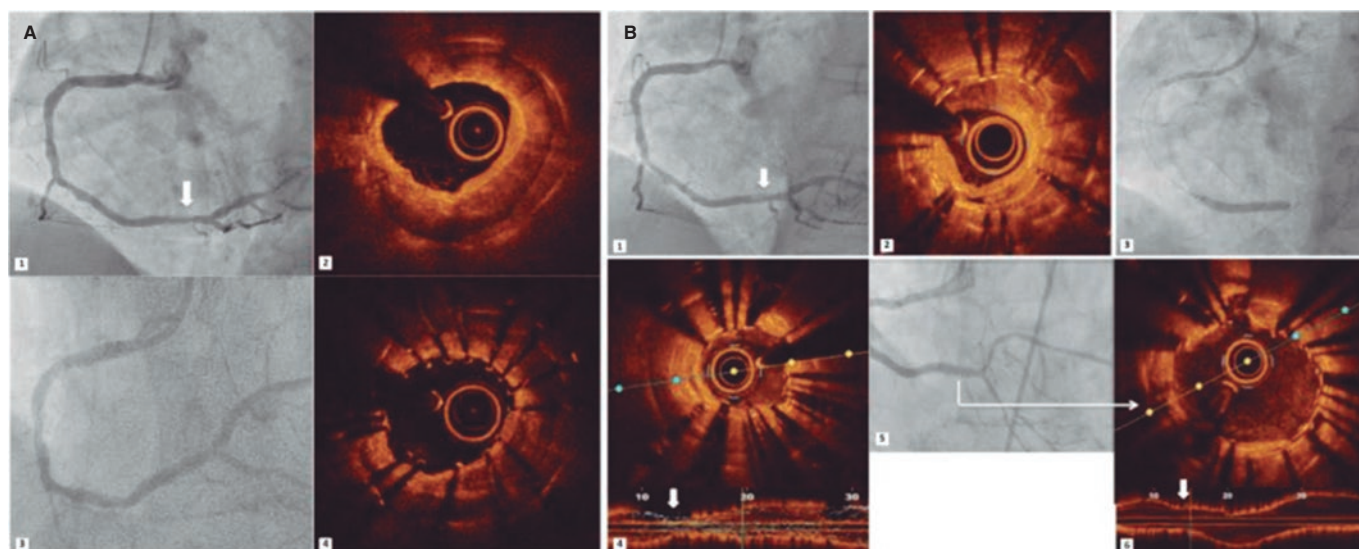
Figure 3. In-stent restenosis and stent underexpansion treated by excimer laser coronary atherectomy (ELCA). Severe in-stent restenosis (ISR) (A1) (arrow) of drug-eluting stent previously implanted in the right coronary artery. Optical coherence tomography (OCT) revealed calcified neoatherosclerosis with a minimum luminal area (MLA) of 1.25 mm^2 (A2). An everolimus-eluting stent (2.75 × 20 mm) was implanted, and despite postdilatation with a 3-mm noncompliant (NC) balloon (A3), subsequent OCT confirmed stent underexpansion (MLA: 2.1 mm^2) (A4). Sixteen months later, critical ISR of the previous stent (B1) (arrow) was noted with heterogeneous neointimal proliferation (B2). Laser atherectomy was performed, followed by dilation with 3- and 3.5-mm NC balloons up to 24 atm, and a 3-mm sirolimus-eluting stent was implanted with acceptable angiographic expansion (B3) but underexpansion on OCT (MLA: 1.5 mm^2) (B4) (arrow). Laser application with contrast injection was repeated and was dilated with a 4 mm NC balloon, achieving adequate stent expansion (MLA: 4.5 mm^2) (B5, B6) (arrow).
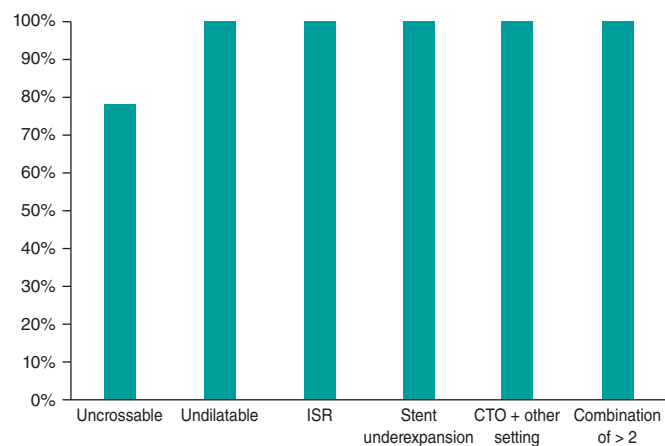

Figure 4. ELCA success rate in the different anatomical settings. ISR, in-stent restenosis, CTO, chronic total occlusion.

therapy adherence. One patient died from advanced heart failure after 3 years of follow-up, despite successful revascularization. Three patients died from noncardiac causes.

The procedural outcomes, clinical outcomes, and major complications are summarized in table 3. No significant differences were observed in the results between male and female patients.

DISCUSSION

The main findings of our study are as follows: *a)* ELCA was associated with a high rate of technical success in severely calcified coronary lesions, whether isolated or combined with other plaque modification techniques, with an acceptable ELCA-related

complications rate. *b)* The success rate was higher in undilatable than in uncrossable lesions and was 100% in peri-stent lesions (stent underexpansion or ISR).

As described in previous series, calcified lesions are associated with higher rates of PCI failure, complications, morbidity, and mortality.[2,16] Although ELCA is known to have no direct effect on calcium, calcified atheromatous plaques have a mixed composition, including lipids, collagen, and other protein fibers.[1,17] The interaction of ELCA with these components, due to its photochemical, photothermal and photokinetic properties, modifies the plaque structure, thus facilitating angioplasty in lesions with severe calcification.[17] Moreover, in some cases, as occurs in our series, ELCA is complementary to other plaque modification techniques, allowing the passage of the microcatheter to introduce specific atherectomy guidewires, or even to allow the passage of the lithotripsy balloon.[14,15] The RASER technique was used in 2 patients and the ELCA-tripsy technique in another patient with technical success in all 3 of them.

There is a lack of contemporary specific series on the use of ELCA in lesions with severe calcification, and data available in the medical literature are contradictory. Bilodeau et al.[18] reported high procedural (93%) and clinical (86%) success in a series of 95 patients with complex coronary lesions, of which 57 had significant calcification. The Laser Veterans Affairs (LAVA) Multicenter Registry[7] evaluated the use of ELCA in 131 target complex coronary lesions, of which 62% were moderately or severely calcified lesions, globally reporting 90% technical and 88.8% procedural success rate, which is consistent with our results. In the LEONARDO study,[19] in which 75% of lesions were calcified, high laser energy levels were shown to be safe and effective (success rate 93.7%). In our series, the highest fluence and frequency were required in 60% of the procedures, with a similar success rate.

Nowadays, the main indication of ELCA is treatment of uncrossable and undilatable lesions. In uncrossable lesions, the laser catheter can

Table 2. Angiographic and procedural characteristics

Angiographic characteristics	
Target vessel	
Left anterior descending coronary artery	31 (38.75%)
Right coronary artery	28 (35.0%)
Circumflex artery	10 (12.5%)
Left main coronary artery	4 (5.0%)
Multivessel disease	56 (71.8%)
Indication for ELCA	
Balloon-uncrossable lesion	32 (40%)
Balloon-undilatable lesion	23 (28.75%)
In-stent restenosis	2 (2.5%)
Stent Underexpansion	5 (6.25)
Chronic total occlusion	6 (7.75%)
Combination of > 2 of the above	10 (12.5%)
Severe calcification as sole indication	2 (2.5%)
Bifurcation	14 (17.7%)
Aorto-ostial	2 (2.5%)
Procedural characteristics	
Access site	
Radial	44 (55.0%)
Femoral	33 (41.2%)
Femoral-radial	3 (3.8%)
Guiding catheter French	
6-Fr	40 (50.0%)
7-Fr	34 (42.5%)
Intracoronary imaging	58 (72.5%)
OCT	48 (60.0%)
IVUS	10 (12.5%)
Laser catheter	
1.4 mm rapid-exchange catheter	2 (2.5%)
0.9 mm rapid-exchange catheter	78 (97.5%)
Maximum fluence (mJ/mm²)	72.97 ± 9.6
Maximum frequency (Hz)	72.7 ±10.4
Number of pulses	5 103 ± 3 120
Total lasing time (sec)	62 [40-91]
Contrast volume (mL)	211 ± 68.0
Fluoroscopy time (min)	30 [22-39]
Radiation dose (Gy/cm²)	103 [79-185]
Procedural time (min)	72 [55-100]
Stent implantation	70 [87.5%]
Stent diameter (mm	3.04 ± 0.50
Stents per procedure	1.8 ± 1.14
Total stent length (mm)	43.7 ± 25.7
Left ventricle assist device used	1 (1.25%)
Timing of PCI (n = 98)	
Ad hoc	22 (27.5%)
Deferred	58 (72.5%)

ELCA, excimer laser coronary atherectomy; OCT, optical coherence tomography; IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention. Data are expressed as no. (%), mean ± standard deviation or median [interquartile range].

Table 3. Procedural and clinical outcomes

Procedural and clinical success	n (%)
ELCA success	73 (91.25%)
Balloon-uncrossable lesion	25 (78.13%)
Balloon-undilatable lesion	23 (100%)
In-stent restenosis	2 (100%)
Stent underexpansion	5 (100%)
Chronic total occlusion	6 (100%)
Combination of > 2 of the above	10 (100%)
Severe calcification as sole indication	2 (100%)
Technical success	73 (91.25%)
Clinical success	70 (87.5%)
Procedural complications	
ELCA-related complications	
Coronary artery perforation	2 (2.5%)
Complications not related to ELCA	
Vascular access complication with major bleeding	1 (1.25%)
Coronary perforation	1 (1.25%)
Flow-limiting dissection	1 (1.25%)
Hemodynamic instability	1 (1.25%)
No-reflow	1 (1.25%)
Ventricular arrhythmia	0 (0%)
In-hospital MACE	
Recurrent angina requiring TLR	0 (0%)
Procedure-related myocardial infarction	1 (1.25%)
New-onset heart failure	0 (0%)
Stroke	0 (0%)
Cardiovascular death	3 (3.75%)
All-cause death	4 (5.0%)
MACE after discharge	
TLR	7 (8.75%)
MI due to stent thrombosis	1 (1.25%)
Death from cardiovascular causes	2 (2.5%)
Non-cardiovascular related death	3 (3.75%)

ELCA, excimer laser coronary atherectomy; MACE, major adverse cardiovascular events; MI, myocardial infarction; TLR, target lesion revascularization.

be advanced over any 0.014˝ angioplasty guidewire that crosses the lesion, unlike other plaque modification techniques. In a multicenter US registry, the success rate for laser-assisted PCI in uncrossable balloon CTO was 95%, which was higher than that for RA (89%) in this setting.[20] In a retrospective study by Karacsonyi et al.,[21] laser use in balloon-uncrossable and balloon-undilatable CTO was associated with higher technical (91.5% vs 83.1%) and procedural (88.9% vs 81.6%) success rates compared with cases without the use of laser. Ojeda et al.[9] conducted a multicenter registry of 126 uncrossable

lesions and reported ELCA success of 81.8%. In that registry, severe calcification was independently associated with ELCA failure, a finding already described in a previous study.[22] In our series (with severe calcification in 100% of patients), the overall ELCA success rate was 91.25%, but the ELCA success in uncrossable lesions was lower than in undilatable lesions (78.1% vs 100%) and similar to that in the series by Ojeda et al.[9] The lower success rate in uncrossable and severely calcified lesions can probably be explained by the different plaque composition and calcium distribution. Furthermore, the higher rate of use of intracoronary imaging could also be associated with better results (72.5% in our series compared with 22.5% reported by Ojeda et al.[9]). Of note, an ELCA success of 78.1% in uncrossable lesions with severe calcification could be a reasonable result, considering that, if even a microcatheter cannot cross the lesion, ELCA may be the only alternative for revascularization.

In other scenarios, the ELCA success rate of our series was high and similar to that of other series. An ELCA success rate of 86% to 93% has been reported in CTOs.[8,23] RA in CTO has been associated with similar success rates (89%-95.6%)[24,25] but with a high rate of slow/no flow phenomena.[24] In patients with stent underexpansion and ISR, ELCA is feasible and effective,[26,27] with 100% ELCA success in our series.

Intravascular imaging is useful to guide calcified coronary stenosis PCI.[28,29] Contemporary rates of intravascular imaging for complex PCI remain low.[30] In our study, intracoronary imaging was used in 72 procedures (73.4%), and intracoronary imaging-guided procedures resulted in a higher success rate. Its lower use in uncrossable lesions can probably be explained by the fact that the intravascular ultrasound/OCT catheter cannot cross the lesion, rather than necessarily being the reason for the lower success rate in this setting.

Limitations

Our study has some limitations. First, it is an observational study with a small sample size. However, to the best of our knowledge, our study represents the largest series of ELCA specifically performed in severely calcified lesions in contemporary PCI. Second, the severity of lesion calcification was initially assessed by conventional coronary angiography, which has only low to moderate sensitivity compared with intravascular ultrasound or OCT. In addition, sometimes the calcium observed by conventional angiography is adventitious, thus not affecting balloon dilation or stent expansion with conventional techniques. However, the use of intracoronary imaging techniques was higher than in previous series and confirmed the severity of calcification in all patients. In addition, a significant number of cases consisted of uncrossable lesions, limiting the use of intracoronary imaging to define the calcification from the beginning of the procedure. Finally, the operators involved in this study were experienced ELCA operators. This may limit the generalizability of our results since ELCA is not available in most centers and requires a learning curve.

CONCLUSIONS

ELCA is a useful tool in severe calcification lesions, with a high success rate, especially in the setting of undilatable or peri-stent lesions. The technique is also reasonably safe, given that it is used in highly complex procedures. Future randomized studies will shed light on its role in the management of severe calcified coronary lesions.

FUNDING

ETHICAL CONSIDERATIONS

All patients signed an informed consent form and approval was obtained from the ethics committee of the center. The study has taken into consideration sex and gender variables according to SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence tool has been used during the preparation of this work.

AUTHORS' CONTRIBUTIONS

A. Jurado-Román conceived and designed the study. L. Cobarro and A. Jurado-Román performed the analysis and wrote the initial draft. L. Cobarro, A. Jurado-Román, D. Tébar-Márquez, S. Vera-Vera, A. García-Escobar, C. Ugueto, C. Contreras, B. Rivero, S. Jiménez-Valero, G. Galeote, and R. Moreno collected the data and reviewed the final version of the manuscript.

CONFLICTS OF INTEREST

R. Moreno is associate editor of *REC: Interventional Cardiology;* the editorial procedure established in the journal has been followed to ensure impartial handling of the manuscript.

A. Jurado-Román is proctor of Philips-Biomenco, Boston Scientific, CSI-World Medica and Medtronic Inc and has received speaker fees from Boston Scientific, Abbott Vascular, World Medica, Biotronik, Philips-Biomenco, and Inari. R. Moreno has received speaker fees from Medtronic Inc, Boston Scientific, Abbott vascular, Biosensors, Biotronik, Edwards Lifesciences, AMGEN, AstraZeneca, and Daiichi Sankyo New Vascular Therapies and Biosensors.

WHAT IS KNOWN ABOUT THE TOPIC?

– Excimer laser coronary atherectomy (ELCA) is a plaque modification technique that has proved to be useful in several scenarios, such as balloon failure (uncrossable or undilatable lesions), chronic total occlusions (CTO), stent underexpansion, in-stent restenosis (ISR) and thrombotic lesions.

– In recent years, incremental operator experience along with the standardization of laser technique has expanded its indications and decreased its complication rates.

– The effectiveness of ELCA in calcified lesions is controversial. On one hand, some ELCA series have described a relationship between severe calcification and laser failure. In contrast, moderate-to-severe calcification is found in more than 60% of cases in some ELCA series with a high success rate, indicating that this technique could be useful in this setting.

– Due to the lack of evidence in this specific scenario, our study aimed to assess the contemporary safety and efficacy of ELCA in severely calcified coronary lesions.

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WHAT DOES THIS STUDY ADD?

– ELCA is associated with a high rate of technical success in severely calcified coronary lesions, whether isolated or combined with other plaque modification techniques, with an acceptable ELCA-related complications rate.

– The success rate is higher in undilatable than in uncrossable lesions and was 100% in peri-stent lesions (stent underexpansion or restenosis). However, in uncrossable lesions, ELCA may be the only alternative for percutaneous revascularization.

– Clinical results after a median follow-up of 15.5 months were favorable, taking into account the complexity of this scenario.

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Debate. Asymptomatic severe aortic stenosis: when should we intervene? The clinician's perspective

A debate. Estenosis aórtica grave asintomática, ¿es el momento de actuar? Perspectiva del clínico

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QUESTION: Can the prevalence of asymptomatic aortic stenosis and its various degrees of severity be estimated in the general population?

ANSWER: Although estimates can be made, they undoubtedly underestimate the true prevalence of asymptomatic aortic stenosis (AS). What we know is that, according to the 2017 European Cardiovascular Disease Statistics, over 6 million new cases of cardiovascular disease are diagnosed each year in Europe, with over 50 million prevalent cases (a 30% increase since 2000). In Spain, this amounts to over 250 000 new cases of cardiovascular disease diagnosed each year, and over 4 million prevalent cases.

If we focus on valvular heart disease, according to the latest Euro Heart Survey, AS is still the most widely diagnosed (41%) and frequently treated (45% of all procedures performed) severe valvular heart disease in the hospital setting. Undoubtedly, AS represents the highest burden of valvular heart disease among patients overall, and is even more significant among older adults. In the Olmsted County registry,[1] the prevalence of AS was 0.5% (4.6% in patients older than 75 years, a rate very similar to that of the AGES-Reykjavík trial,[2] where the prevalence of severe AS in patients older than 70 years was 4.3%.)

If we look at asymptomatic patients, data on the true prevalence are available but they are drawn from indirect sources. Spain has played a major role in our ability to estimate the prevalence in these patients. In the registry of Ferreira et al.[3] the prevalences of sclerosis was 45.5% and that of stenosis was 3%. More recently, a study conducted by our group[4,5] in vaccination centers found undetected aortic sclerosis in 53.4% of the patients and undetected AS in and 4.2%.

Therefore, based on the population prevalence data obtained and the current and projected composition of the Spanish population for the next 40 years, it is estimated that 470 000 Spaniards currently have undiagnosed AS. If the expectations for population growth and distribution of Spain's National Statistics Institute are met, and if the proportion of diagnosed or treated cases vs undetected cases doesn't change, the number of people with undiagnosed AS would be close to 1 million by 2060. If we assume that 10% of all undetected cases of AS are severe, were talking about nearly 100 000 cases of undiagnosed severe AS and, therefore, not followed-up or potentially treated. Let's not forget that, currently, nearly 4500 cases of severe AS are treated each year, which helps put the problem in perspective.

Q.: How should patients with severe AS who remain asymptomatic be approached from a diagnostic standpoint?

A.: First, it is essential to make sure that a patient with severe AS is truly asymptomatic. The key is to delve deep into the patient's past medical history and have an expert review the EKG performed. If stenosis is genuinely severe and asymptomatic, there are data that will eventually lead us to start early treatment. We should remember to assess the presence of ventricular dysfunction, symptom onset during exercise, a fall in blood pressure on exertion, marked elevations of brain natriuretic peptide levels, very extensive coronary artery calcification, and rapid reduction in aortic area during disease progression; these are clear indications that we need to act quickly. This is much more important with today's well-established, low-risk percutaneous techniques. We should remember that, with the rapid advancement of the technique since the introduction of transcatheter aortic valve implantation (TAVI), practices that we never thought to question, such as waiting for symptom onset or starting treatment before progression to severe disease, may have become outdated.

I think that the best time to treat asymptomatic patients with severe AS is when they develop left ventricular decompensation. Data such as brain natriuretic peptide levels, the EKG strain pattern, T_1 mapping, and delayed enhancement on magnetic resonance imaging help identify high mortality risk in these patients. Therefore, stratifying heart damage adds additional prognostic value to the traditional clinical risk factors for predicting survival in asymptomatic AS.

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Ongoing trials[6,7] may lead us to consider earlier interventions even in asymptomatic patients.

Q.: What relevant evidence could support the use of aortic valve replacement in a case of truly asymptomatic severe aortic stenosis?

A.: There is evidence from patients who underwent surgery that supports the idea of treating asymptomatic patients. The AVATAR trial[8] demonstrated that, in asymptomatic patients with severe AS, early surgery reduced the composite primary endpoint of all-cause mortality, acute myocardial infarction, stroke, and heart failure-related admissions compared with conservative treatment.

The EARLY TAVR trial (NCT03042104) will examine the safety and efficacy profile of TAVI with the SAPIEN 3 or SAPIEN 3 Ultra valves vs clinical follow-up in asymptomatic patients with severe AS. The aim of this trial is to compare outcomes between patients undergoing valve replacement early in the disease and those undergoing clinical surveillance.

However, given the natural progression of AS and the low morbidity and mortality of TAVI, the idea of treating AS at an earlier stage of the disease has been suggested. The recent VALVENOR trial[9] demonstrated that, compared with the general population, patients with moderate symptomatic AS had more cardiovascular mortality than those with mild AS (although still lower than that of patients with severe AS). In this regard, the PROGRESS (NCT04889872), TAVR UNLOAD (NCT02661451), and landmark EXPAND TAVR II trials (NCT05149755) assess TAVI vs clinical surveillance in symptomatic patients with moderate AS. While cautious optimism is warranted, it's important to acknowledge certain potential limitations. Also, we must be aware that preventing valve degeneration is an important area of current research and that replacing the native valve with a prosthetic valve is not a permanent solution to the problem. Additionally, as we treat progressively younger patients, it is important to understand the anatomical limitations imposed by the need for future valve-in-valve procedures and the durability of the valves.

Q.: How does your center currently manage these patients?

A.: It's obvious that our center has radically changed the diagnosis, follow-up, and treatment of these patients since we set up the Valve Clinic (2 clinical cardiologists and 1 heart valve clinical nurse specialist) 7 years ago. Diagnoses are reached following a standardized protocol and always with the same echocardiography machine, which is configured to only perform valve EKGs. This guarantees acceptable variability and standardization. Once the clinical cardiologist has decided that a patient needs treatment, we stay in close contact with other professionals specialized in the management of this type of patient. This undoubtedly enhances the quality of care. Data are reported to the hospital annually and are then published, including all possible complications and outcomes. Surgeons also present data on their surgically-treated patients on a yearly basis. We're lucky to have excellent clinical cardiologists, operators, and surgeons at Hospital Ramón y Cajal with broad experience in the management of patients with valvular heart disease and with published data that can be audited.

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence has been used in the preparation of this work.

CONFLICTS OF INTEREST

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Debate. Asymptomatic severe aortic stenosis: when should we intervene? The interventional cardiologist's perspective

A debate. Estenosis aórtica grave asintomática, ¿es el momento de actuar? Perspectiva del intervencionista

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QUESTION: What relevant evidence could support aortic valve replacement today in cases of true severe asymptomatic aortic stenosis? Are there any studies on both techniques, surgery and transcatheter implantation?

ANSWER: Ross and Braunwald's[1] description of the outcomes of patients with severe symptomatic aortic stenosis (AS) almost 60 years ago laid the foundations for the indication for surgery—the first-line therapy to date—to treat this disease, although transcatheter aortic valve implantation (TAVI) is also indicated. At a time when surgery was the only therapeutic option available, with mortality rates close to 3% to 4%, nobody thought of treating asymptomatic patients, who had a risk of sudden death of nearly 1%. These findings were confirmed by later studies, and the treatment of asymptomatic AS continued to lack evidence until the first decade of the 21st century when observational studies with small series of patients with severe asymptomatic AS (Vmax ≥ 4 m/s and mean gradient ≥ 40 mmHg) began to be published. In all of them, the results favored early surgical treatment. In the study of 197 patients by Kang et al.,[2] the primary endpoint was a composite of operative and follow-up mortality. The 6-year cardiac and all-cause mortality rates were 0% and 2 ± 1% in the surgical group compared with 24 ± 15% to 32 ± 6% in the conservative treatment group. The CURRENT AS[3] registry of Taniguchi et al, with 1808 patients (291 in the surgical group and 1517 in the conservative treatment group) favored the surgical group in terms of overall mortality (15.4% vs 26.4%; *P* < .009) and heart failure-related admissions (3.8% vs 19.9%; *P* < .0001). The only randomized clinical trials published to date comparing conservative vs surgical treatment are the RECOVERY[4] and the AVATAR[5] trials, both with a small number of patients (145 and 157, respectively), and both with results favorable to surgery. In the RECOVERY trial, the primary endpoint was a composite of procedural and cardiovascular mortality during follow-up, with rates of 1% in the surgical group and 15% in the conservative treatment group (hazard ratio [HR], 0.09; 95%CI,

0.01-0.67). The 4- and 8-year cumulative incidence rates of the primary endpoint remained at 1% in the surgical group vs 6% and 26% (*P* = .003) in the conservative treatment group. In the AVATAR trial, the primary endpoint was a composite of all-cause mortality, myocardial infarction, stroke, or unplanned heart failure-related admission, with rates of 15.22% and 34.7% at the 3-year follow-up (HR, 0.46; 95%CI, 0.23-0.9).

The first TAVI was performed back in 2002. Since then, we have come a long way regarding indications—although it's only a short time—because in 20 years, TAVI has been recognized as the treatment of choice for inoperable and high surgical risk patients, with similar results compared to those of surgery in moderate and low surgical risk patients. These trials have focused on symptomatic patients. Several trials are under way in asymptomatic patients, EARLY TAVR (NCT03042104) and EVOLVED (NCT03094143), and their results will be published soon, but until then, the only evidence to date supporting treatment in asymptomatic patients is surgical.

Q.: When the decision is made to intervene in cases of severe asymptomatic aortic stenosis, on what grounds should the choice be made between surgery and TAVI? Would it be any different from the choice in a symptomatic case?

A.: The current clinical guidelines on the management valvular heart disease of the European Society of Cardiology[6] still focus on the indication for treating AS based on symptoms; asymptomatic AS is not included in this indication, unless there are laboratory or echocardiographic predictors of rapid symptom progression. As explained earlier, there is currently more evidence on surgery in asymptomatic patients. However, a more in-depth analysis of the studies reveals 2 important facts. One is that the mean age was generally low: 65 years in the RECOVERY trial and 68 years in the AVATAR trial, and was very similar in registries. The other is that

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the causes of AS are highly variable: in the RECOVERY trial, 61% of the patients had bicuspid valves, 33% degenerative valves, and 6% rheumatic valves. In the AVATAR trial, 84.7% had degenerative valves, 14% bicuspid valves, and 1% rheumatic valves.

In Spain, where life expectancy is one of the longest worldwide—82 years in men and 87 years in women in 2023—most patients treated with TAVI have degenerative AS, and the incidence of bicuspid valves is lower than that reported by studies, which means that using the same criteria is challenging. However, it seems clear that severe or very severe AS, as included in the studies, shows better mid- and long-term survival rates when treated early, while asymptomatic. The severity criteria included in the studies (Vmax ≥ 4.5 m/s, mean gradient ≥ 50 mmHg) help us select those patients who benefit the most from early treatment. On the issue on what treatment we should use (surgery or TAVI), the decision is more complicated due to the lack of evidence on TAVI. As mentioned earlier, the average patients we treat are octogenarians. In some cases, AS is found during a routine examination, and if they are truly asymptomatic (because octogenarians often cut down on activity and have difficulty recognizing their own physical limitations) and meet severity criteria, an early intervention will result in better quality of life and fewer procedural complications. In my opinion, applying the same criteria used with symptomatic patients is beneficial for patients, meaning that, in patients with low-to moderate surgical risk, if we accept the results of TAVI trials,[6-8] the transcatheter option is entirely acceptable. A different type of patient are those under follow-up because they have bicuspid valves or rheumatic disease. These patients are often younger and the indication for surgical valve replacement is clearer because TAVI still has limitations that need to be resolved in terms of durability, the need for new procedures if there is prosthetic valve degeneration, access to coronary arteries, and the treatment of bicuspid valves, which also remains poorly established. Additionally, TAVI is associated with a higher rate of pacemaker implantation, which, in young patients, is related to new comorbidities and various effects on ventricular function.

Therefore, the choice would be TAVI for octogenarians and surgery for younger patients. I would set patients from 75 to 80 years apart who could potentially receive transcatheter treatment based on their own preferences.

On the issue of whether treatment would differ in asymptomatic compared with symptomatic patients, in my opinion, this would not be the case. AS is a continuum in which symptoms appear sooner or later. Although it seems that we can base our decisions on evidence when treating symptomatic AS, we have to think that the benefit to the patient is greater as physical and pathophysiological conditions will always be better before symptom onset. In fact, sometimes the changes triggered by symptomatic AS can be irreversible. Treating asymptomatic patients requires both us and surgeons, who have already reduced mortality down to 1% in these patients, more meticulous approaches regarding valve selection and implantation, correctly selecting the valve while minimizing risks and complications, since patients should benefit in the short- and long-term.

Q.: Any considerations on the TAVI technique that should be used in these cases?

A.: When we decide to perform TAVI in a symptomatic patient, we assess the anatomical and clinical factors involved. The same applies to asymptomatic patients: on the one hand, if the patient is young and has a bicuspid valve, the valve selected should have enough radial strength, a low pacemaker implantation rate, and give us room to plan a second TAVI in the future while securing access to the coronary arteries. If a self-expanding supra-annular

valve is selected, the current tendency is to place the prosthetic valve as high as possible with respect to the annulus to minimize the risk of pacemaker implantation. This may compromise access to the coronary arteries, which is why, commissural alignment should be attempted, as far as possible. To avoid complications such as stroke, which can be devastating in young patients, the use of embolic protection devices is justified, although the only randomized clinical trial published to date has not shown any benefits in specific subgroups for stroke in general (primary endpoint) as opposed to disabling stroke (not the primary endpoint). In older asymptomatic patients with degenerative AS, the implantation technique follows the same pattern used with symptomatic patients.

Q.: What is the current management of these patients in your center?

A.: At the Álvaro Cunqueiro Hospital, all patients are discussed in a heart team session, where the treatment criteria are more or less clear. Asymptomatic patients come through various routes: one is patients with valvular heart disease under clinical surveillance who develop severity criteria during follow-up. If the patient is older than 80 years, the decision is often to use the transcatheter approach, from 75 to 79 years, either of the 2 treatments would be fine, and the patient's preference is a consideration, and if the patient is younger than 75 years, the decision is often to perform surgical valve replacement. Patients with bicuspid valves are often young and initially referred for surgical treatment.

In other patients, AS is found during routine examination due to another disease. Here, there's a subgroup that requires quick decision-making: patients with neoplasms or interventions that cannot be delayed for too long. In these cases, transcatheter treatment is the chosen one because implantation is possible once the results from the computed tomography become available. The intervention is performed within the next few days, with rapid recovery, before the next intervention. If the patient is young and has a bicuspid valve, a balloon-expandable valve is often used. If the patient is older and doesn't have coronary artery disease, a self-expanding valve is used. If the patient has coronary artery disease to be treated after the intervention, if necessary, a self-expanding valve with easy access to the coronary arteries is often implanted. If vascular access is suboptimal, a self-expanding valve is also the preferred choice due to its better profile.

If asymptomatic patients don't have any other conditions requiring immediate treatment, they are treated as if they were symptomatic patients, except for patients with criteria of very severe AS (Vmax ≥ 5 m/s, mean gradient ≥ 60 mm Hg, and progression of Vmax ≥ 0.3 m/s/year), who are treated preferentially.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence has been used in the preparation of this work.

CONFLICTS OF INTEREST

J. A. Baz Alonso is a proctor for Biosensors for the Allegra valve implantation, and advisor to Medtronic Iberia on structural heart diseases.

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Interventional catheterization in pediatric patients after Fontan procedure

Cateterismo intervencionista en pacientes pediátricos tras cirugía de Fontan

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To the Editor,

The advances made in surgical techniques followed by the best candidate selection process possible and optimal preparation of patients eligible for surgery have contributed to reducing early postoperative mortality in patients treated with the Fontan procedure.[1] However, the balance provided by the Fontan procedure is precarious and can fail for multiple reasons that can be resolved through interventional catheterizations (IC).[2-4]

This study describes the experience of our center performing IC and focuses on the type of interventional procedures performed and predictors of these.

We conducted a retrospective study of all patients < 18 years-old who underwent a Fontan procedure from January 2000 through December 2021 and were treated with IC due to suspected anatomical injury detected by echocardiography (annually) or magnetic resonance imaging (at 10 years and then every 3 years) or complications like protein-losing enteropathy, plastic bronchitis or hepatopathy. Since 2017, scheduled catheterizations are performed 10 years after the Fontan procedure.

All patients gave their prior written informed consent, and the study was approved by the hospital ethics committee. Possible sex and gender variables have been considered in accordance with the SAGER guidelines.

Descriptive statistics of the demographic, anatomical, hemodynamic, and surgical variables was used. Normally distributed variables were expressed as mean and standard deviation while those without a normal distribution were expressed as median and interquartile range [IQR]. Kaplan-Meier curves were drawn to estimate the IC-free survival rate. To identify predictors of the need for IC, univariate Cox logistics regression analysis was conducted. Variables with significance levels < .2 were included in the multivariate analysis. Also, hazard ratios (HR) with a 95% confidence interval (95%CI) were estimated.

A total of 74 patients treated with a Fontan procedure were identified. Their demographic, anatomical, and pre-catheterization characteristics are shown on table 1. After a median follow-up of 10.3 years [IQR, 5.3-13.3], a total of 59 IC were performed on 35 patients (47%) for a total 79 interventional procedures. The most common ones were embolization of collaterals between systemic and pulmonary veins (26.6%), stent implantation or dilation into the pulmonary branches (20.3%), closure of fenestration (19%), and embolization of aortopulmonary collaterals (16.5%). Other interventional procedures included fenestration dilation (5.1%), Fontan stent implantation or dilation (5.1%), aortic stent implantation or dilation (3.8%), endocavitary pacemaker implantation (1.3%), embolectomy (1.3%), and embolization of antegrade flow (1.3%). A total of 20, 9, 4, 1, and 1 patients were treated with 1, 2, 3, 4, and 5 IC, respectively.

The IC-free survival rate was 63% and 45% at 5 and 10 years, respectively (figure 1A). No deaths were reported associated with cardiac catheterizations. A total of 4 patients (5%) experienced complications associated with the catheterizations (pulmonary thromboembolism, brachial neuropraxia, vasoactive drug administration during the procedure, and pulmonary atelectasis).

The diagnosis of hypoplastic left heart syndrome (HR, 2.62; 95%CI, 1.18-5.78), and the values of mean pulmonary artery pressure (HR, 1.2; 95%CI, 1.02-1.41), the transpulmonary gradient (HR, 1.64; 95%CI, 1.21-2.22), and the McGoon index (HR, 0.18; 95%CI, 0.07-0.44) prior to the Fontan procedure behaved as independent predictors of the need for IC after this surgery (figure 1B).

In our patients, the rate of interventional procedures performed (47%) is similar to that reported in the series by Downing et al.[3] with an IC-free survival rate of 53% at 15 years. Although the number of procedures performed is quite similar, in their case, the closure of fenestration was the most common procedure of all due to their high rate of fenestrated Fontan (90%) compared to ours (35%).

Nonetheless, when our series was compared to others with older patients, significant differences were found. A total of 49% of the patients from the series of Van Dorn et al.[4] (1978 through 2002) were treated with a traditional atriopulmonary connection. Most interventional procedures were pacemaker implantation or replacement (26%) or arrhythmia ablation (20%).

Our clinical practice attempts the closure of the fenestration 6 months after the Fontan procedure if the patient's disease progression is favorable, pressure remains < 16 mmHg during the

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Table 1. Characteristics of patients, types of interventional procedures, and time elapsed since the Fontan procedure

Characteristics	Age at the Fontan procedure
Type of heart disease	
Hypoplastic left heart syndrome	19 (25.6)
Tricuspid atresia	15 (20.3)
Complex heart disease with functionally univentricular heart	13 (17.5)
Double-inlet left ventricle	12 (16.2)
Pulmonary atresia with intact septum	9 (12.2)
Ebstein anomaly	3 (4.1)
Heterotaxy	3 (4.1)
Dominant right ventricle	25 (33.8)
Masculine sex	40 (54.1)
Norwood surgery	20 (27)
Age at the Fontan procedure (months)	62.8 ± 27.6
Weight at the Fontan procedure (kg)	17.3 ± 5.4
Type of Fontan procedure	
Extracardiac	67 (90.5)
Lateral tunnel	7 (9.5)
Fenestrated	26 (35.1)
Pre-Fontan catheterization data	
mPAP (mmHg)	12.2 ± 2.3
TPG (mmHg)	3.6 ± 1.6
iPVR (WU·m²)	1.1 ± 0.5
EDVP (mmHg)	10.4 ± 2.7
Qp/Qs	0.5 ± 0.1
Nakata index (mm²/m²)	243.8 ± 85.2
McGoon index	2 ± 0.5

Type of interventional procedure	Time elapsed since the Fontan procedure, months
Embolization of SV-PV collaterals	72.3 [35-90.5]
Stent implantation/dilation into the pulmonary branches	46.3 [3-81.6]
Fenestration closure	15.6 [9.3-23.3]
Embolization of aortopulmonary collaterals	25.4 [6.7-93.1]
Fenestration dilation	3.9 [0.2-63.3]
Stent implantation/dilation into Fontan. SVC or IVC	138.4 [34.3-152.4]
Stent implantation/dilation into the aorta	85.4 [4.4-122.2]
Endocavitary pacemaker implantation	82.4*
Embolectomy	0.26*
Embolization of antegrade flow	1.43*

EDVP, end-diastolic ventricular pressure; iPVR, indexed pulmonary vascular resistances; IVC, inferior vena cava; mPAP, mean pulmonary artery pressure; Qp/Qs, pulmonary to systemic flow ratio; SV-PV, systemic vein-pulmonary vein; SVC, superior vena cava; TPG: transpulmonary pressure gradient; WU, Wood units.
Data are expressed as no. (%), mean ± standard deviation, and median [interquartile range]; those with only 1 value express absolute time in months.
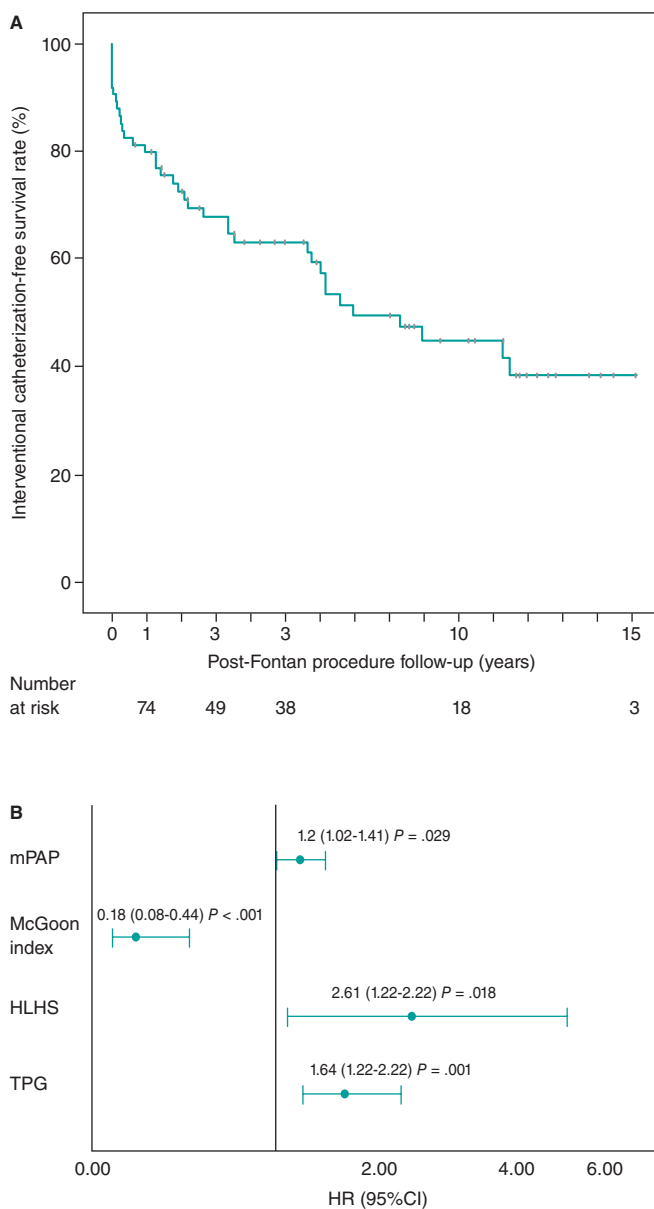* 1 patient only.

Figure 1. **A**: Kaplan-Meier curve of interventional catheterization-free survival after Fontan procedure. **B**: Independent predictors of the risk of interventional catheterization. 95%CI, 95% confidence interval; HLHS: hypoplastic left heart syndrome; HR, hazard ratio; mPAP, mean pulmonary artery pressure; TPG: transpulmonary pressure gradient.

occlusion test, and proper cardiac output is preserved (> 2 L/min/m² with a decrease of < 20% compared to baseline levels).

The presence of aortopulmonary collaterals has proven to have a negative effect on Fontan circulation, thus extending the duration of pleural effusions and causing ventricular volume overload. Therefore, we delve into an aggressive search and embolization of these collaterals in the catheterizations performed before and after the Fontan procedure.

The lack of stenosis in the Fontan conduit and pulmonary branches is essential to keep proper hemodynamics in Fontan circulation. Therefore, it seems logical to treat stenoses even in asymptomatic patients.

Regarding the risk factors associated with performing IC, the diagnosis of hypoplastic left heart syndrome was seen as an

independent predictor of this event in both the series of Downing et al.[3] and our own. Elevated pulmonary pressures and resistances, and smaller pulmonary arteries are known factors of poor prognosis in this population.

FUNDING

None reported.

ETHICAL CONSIDERATIONS

All patients signed the informed consent and the study was approved by the hospital's ethics committee. Possible sex and gender variables have been considered in accordance with the SAGER guidelines.

DECLARATION OF USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence has not been used during the preparation of this manuscript.

AUTHORS' CONTRIBUTIONS

A. Mendoza, and L. Albert: study idea, and data mining and analysis. M. Flores, D. Herrera, B. Toral, and A. Caro: manuscript review and edition.

CONFLICTS OF INTEREST

None whatsoever.

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Relationship between membranous septum length and need for pacemaker implantation after transcatheter aortic valve implantation

Relación entre longitud del septo membranoso y necesidad de marcapasos tras implante de válvula aórtica

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To the Editor,

Transcatheter aortic valve implantation (TAVI) can trigger significant conduction disorders due to the mechanical compression caused by the transcatheter heart valve. This is because of the proximity between the aortic annulus, the atrioventricular node, and the membranous septum (MS) of the left ventricular outflow tract. The rate of pacemaker implantation after TAVI ranges from 4% to 33%.[1]

This retrospective analytical study included symptomatic patients with severe aortic stenosis referred for multidetector computed tomography as part of the TAVI protocol from December 2012 through October 2022. Written informed consent was obtained from all patients prior to the tomography scan by obtaining approval to conduct the study. We excluded patients with bicuspid aortic valve anatomy, pacemaker carriers, and those with previous

surgical bioprosthetic valve. The aim of this study was to determine whether MS length is associated with the need for pacemaker implantation after TAVI. MS length was measured as the maximum distance from the plane of the aortic annulus to the top of the muscular portion of the ventricular septum in the coronal plane during systole (figure 1A,B).[2] Qualitative variables were analyzed using the chi-square test or Fisher exact test, while quantitative variables were analyzed using the Mann-Whitney U test. P values < .005 were considered statistically significant. A receiver operating characteristic (ROC) curve was constructed to assess the predictive accuracy of MS length for pacemaker implantation. Data were analyzed using the IBM SPSS statistical software package, version 26 (United States).

A total of 134 consecutive patients were assessed: 71 (53%) were men and the mean age was 75.5 ± 7.6 years.

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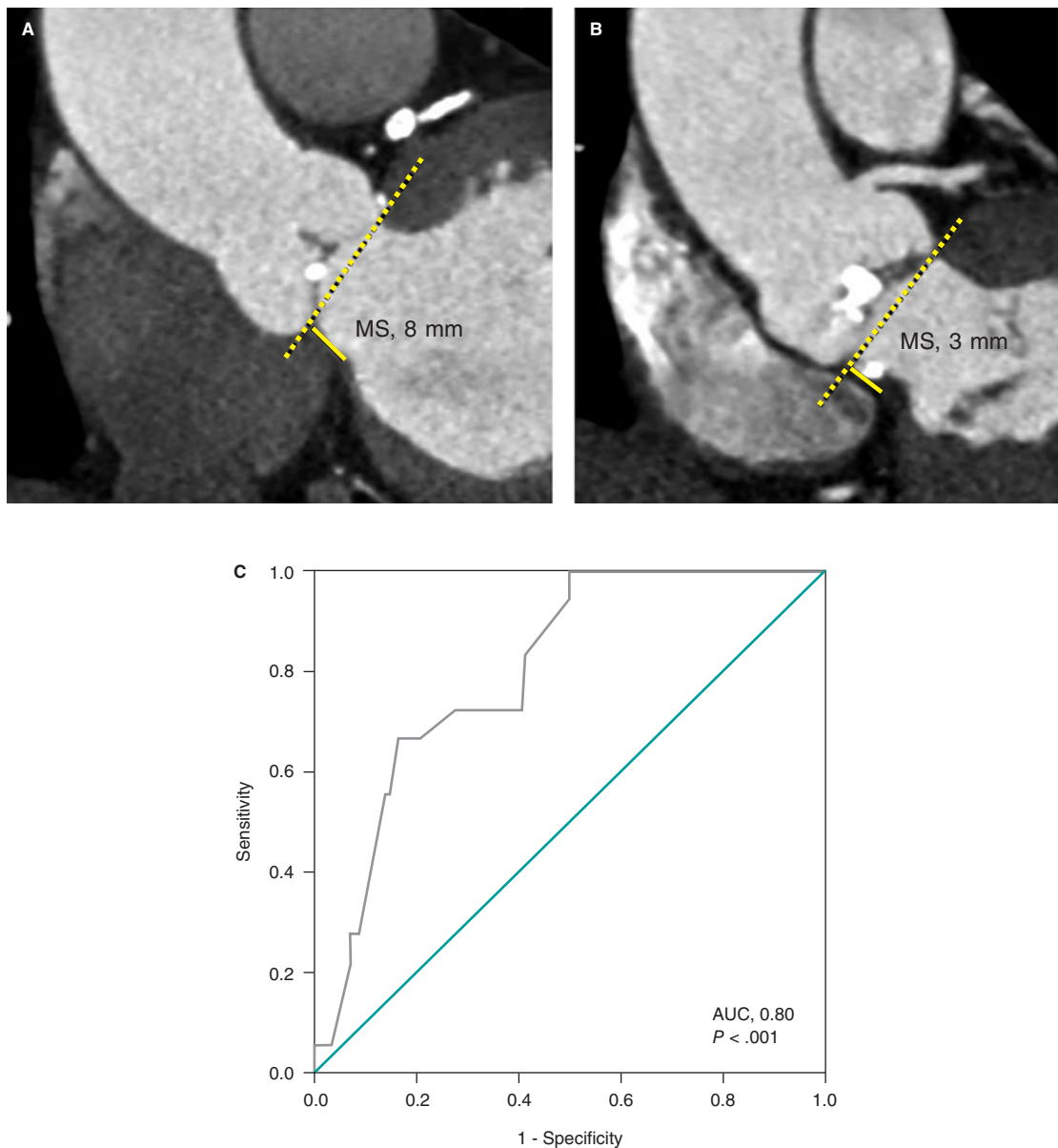*Scientific letters. REC Interv Cardiol. 2024;6(1):46-54*

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Figure 1. Measurement of membranous septum (MS) length by multidetector computed tomography in the coronal view. **A:** patient with an 8-mm MS not requiring no pacemaker implantation. **B:** patient with a 3-mm MS and left ventricular outflow tract calcification who underwent pacemaker implantation due to third-degree atrioventricular block after transcatheter aortic valve implantation. **C:** receiver operating characteristic (ROC) curve. Membranous septum length as a predictor of pacemaker implantation. The area under the curve (AUC) was 0.80 with cut-off, sensitivity, and specificity values of 5.5 mm, 0.67%, and 0.84%, respectively (*P* < .001).

In the pre-TAVI electrocardiogram, 117 patients (87.3%) were in sinus rhythm, 14 (10.4%) had atrial fibrillation, and 34 (25.4%) had conduction disorders (table 1).

The most commonly used balloon-expandable valve was Edwards SAPIEN 3 (Edwards Lifesciences, United States), which was used in 60 patients (44.8%), while the most widely used self-expanding valve was Evolut R, which was implanted in 17 patients (12.7%) (table 1).

After TAVI, 16 patients (11.9%) developed third-degree atrioventricular block, and 12 (9%) developed persistent new left bundle branch block (table 1).

Pacemaker implantation was performed in 18/134 patients (13.4%). Of these, balloon-expandable valves were implanted in 12/82

(14.6%), while self-expanding valves were implanted in 6/52 (11.5%). There was a significant correlation between CoreValve (Medtronic, United States) and pacemaker implantation (odds ratio [OR], 5.24; 95% confidence interval [CI], 1.32-20.86; *P* = .029).

In our Mexican population, the mean body mass index (BMI) was 26 kg/m^2, while MS length was 6.86 mm. In patients receiving a pacemaker (n = 18), MS length was significantly shorter (5.3 ± 1.2 vs 7.1 ± 1.7 mm; *P* < .001), with a cut-off value of 5.5 mm (*P* < .001) (figure 1C). On univariate analysis, the OR for the association between MS length < 5.5 mm and need for pacemaker implantation was 6.80 (95%CI, 2.36-19.58).

The MS lengths reported in the literature vary. In a Japanese population with a mean BMI of 21.7 kg/m^2, the mean MS length

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Table 1. Clinical and electrocardiographic characteristics before and after TAVI, tomographic parameters, types of transcatheter heart valve, and complications after TAVI

Variables	Total n = 134	With pacemaker implantation n = 18	Without pacemaker implantation n = 116	P
Clinical characteristics				
Age, years	75.5 ± 7.6	76.2 ± 7.8	75.5 ± 7.5	.63
Masculine sex, n (%)	71 (53%)	12 (66.7%)	59 (51%)	.21
BMI, kg/m^2	26 ± 4.3	28 ± 6.8	25.7 ± 3.7	.2
Hypertension, n (%)	91 (67.9%)	10 (55.6%)	81 (69.8%)	.23
Ischemic heart disease, n (%)	74 (55.2%)	9 (50%)	65 (56%)	.63
Diabetes mellitus, n (%)	43 (32.1%)	8 (44.4%)	35 (30.2%)	.23
Dyslipidemia, n (%)	36 (26.9%)	5 (27.8%)	31 (26.7%)	1
Smoking, n (%)	33 (24.6%)	3 (16.7%)	30 (25.9%)	.56
Kidney disease, n (%)	18 (13.4%)	3 (16.7%)	15 (12.9%)	.71
Electrographic characteristics prior to TAVI				
Rhythm				
Sinus, n (%)	117 (87.3%)	17 (94.4%)	100 (86.2%)	.47
Atrial fibrillation, n (%)	14 (10.4%)	0	14 (12.1%)	.21
Flutter, n (%)	3 (2.2%)	1 (5.6%)	2 (1.7%)	.35
Conduction disorder				
RBBB, n (%)	13 (9.7%)	4 (22.2%)	9 (7.8%)	.07
LBBB, n (%)	10 (7.5%)	2 (11.1%)	8 (6.9%)	.66
First-degree AVB, n (%)	8 (5.9%)	3 (16.7%)	5 (4.3%)	.13
LBBB + First-degree AVB, n (%)	2 (1.5%)	0	2 (1.7%)	1
Incomplete left bundle branch block, n (%)	1 (0.7%)	0	1 (0.9%)	1
Tomographic parameters				
MS length, mm	6.86 ± 1.72	5.3 ± 1.2	7.1 ± 1.7	< .001
Presence of LVOT calcification, n (%)	39 (29.1%)	9 (50%)	30 (25.9%)	.036
Type of transcatheter heart valve				
Balloon-expandable				
Edward SAPIEN 3, n (%)	60 (44.8%)	8 (44.4%)	52 (44.8%)	.9
Edward SAPIEN, n (%)	14 (10.4%)	3 (16.7%)	11 (9.5%)	.4
Edward SAPIEN XT, n (%)	8 (6%)	1 (5.6%)	7 (6%)	1
Self-expandable				
Evolute R, n (%)	17 (12.7%)	1 (5.6%)	16 (13.8%)	.47
ACCURATE Neo, n (%)	14 (10.4%)	0	14 (12.1%)	.21
Portico, n (%)	11 (8.2%)	1 (5.6%)	10 (8.6%)	1
CoreValve, n (%)	10 (7.5%)	4 (22.2%)	6 (5.2%)	.029
Electrocardiographic characteristics after TAVI				
Third-degree AVB, n (%)	16 (11.9%)	16 (88.9%)	0	< .001
Isolated persistent new-onset LBBB, n (%)	10 (7.4%)	0	10 (8.6%)	.5
Persistent LBBB + AF + NSVT, n (%)	1 (0.8%)	1 (5.6%)	0	.13

(Continues)

Scientific letters. REC Interv Cardiol. 2024;6(1):46-54

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Table 1. Clinical and electrocardiographic characteristics before and after TAVI, tomographic parameters, types of transcatheter heart valve, and complications after TAVI *(continued)*

Variables	Total n = 134	With pacemaker implantation n = 18	Without pacemaker implantation n = 116	*P*
Persistent LBBB + nodal rhythm, n (%)	1 (0.8%)	1 (5.6%)	0	.13
Transient third-degree AVB, n (%)	8 (6%)	0	8 (6.9%)	.65
First-degree AVB, n (%)	6 (4.5%)	0	6 (5.2%)	.41
Transient LBBB, n (%)	4 (3%)	0	4 (3.4%)	.56
Isolated AF, n (%)	2 (1.5%)	0	2 (1.7%)	.75
Transient nodal rhythm, n (%)	1 (0.8%)	0	1 (0.9%)	.87
Flutter, n (%)	1 (0.8%)	0	1 (0.9%)	.87
Complications after TAVI				
Local: Iliac or femoral artery dissection, hematoma	8 (6%)	0	8 (6.9%)	.30
Pericardial effusion/Tamponade	3 (2.2%)	1 (5.6%)	2 (1.7%)	.35
Ischemic stroke	3 (2.2%)	0	3 (2.6%)	.35
Kidney disease	3 (2.2%)	1 (5.6%)	2 (1.7%)	.35
Intraoperative mortality	5 (3.73%)			
Massive ischemic stroke	1 (0.8%)	0	1 (0.9%)	.86
Hypovolemic shock due to iliac artery perforation	1 (0.8%)	0	1 (0.9%)	.86
Cardiogenic shock due to acute myocardial infarction	3 (2.2%)	0	3 (2.6%)	.65
Out-of-hospital mortality > 30 days after TAVI				
Non-cardiac causes	4 (2.98%)	0	4 (3.4%)	.55

AF, atrial fibrillation; AVB, atrioventricular block; BMI, body mass index; LBBB, left bundle branch block; LVOT, left ventricular outflow tract; MS, membranous septum; NSVT, non-sustained ventricular tachycardia; RBBB, right bundle branch block; TAVI, transcatheter aortic valve implantation.

was 5.3 mm ± 1.3 mm in pacemaker carriers vs 6.6 mm in noncarriers (P = .001).[3] In a North American population with a mean BMI of 28 kg/m^2, MS length was 7.5 mm with measurements of 6.4 mm ± 1.7 mm in pacemaker carriers vs 7.7 mm ± 1.9 mm in patients without pacemakers (P = .001).[4]

Pre-existing right bundle branch block was a risk factor for high-degree atrioventricular block. Among the 13 patients with pre-existing right bundle branch block, 4 (22.2%) underwent pacemaker implantation (P = .07). The mean MS length was 7.22 mm with measurements of 5.78 mm in the 4 pacemaker carriers vs 7.86 mm in noncarriers (P = .063).

Ten patients had baseline left bundle branch block with a mean MS length of 5.85 mm. In the 2 patients who underwent pacemaker implantation, the mean length was 4.8 mm vs 6.11 mm in those without a pacemaker (P = .3).

A significant association was found between left ventricular outflow tract calcification with pacemaker implantation (OR, 2.86; 95%CI, 1.04-7.89; P = .036) and conduction disorders (OR, 2.65; 95%CI, 1.22-5.72; P = .012).

None of the 14 patients with pre-existing atrial fibrillation underwent pacemaker implantation. Mentias et al.[5] reported that the rate of pacemaker implantation was significantly lower (P = .001) in patients with pre-existing atrial fibrillation (24.9%) than in those with baseline sinus rhythm (25.3%) and new-onset atrial fibrillation (28.2%).

The rate of new-onset left bundle branch block after TAVI ranges from 8% to 30% with balloon-expandable valves and from 22% to 50% with self-expanding valves such as CoreValve.[2] In the present study, the rate was lower, at 9% (12/134), with 5/82 patients (6.1%) being implanted with balloon-expandable valves and 7/52 patients (13.5%) with self-expanding valves. Sammour et al.[6] demonstrated that the depth of transcatheter heart valve implantation is a predictor of new left bundle branch block. A limitation of the present study is that we did not measure the depth of valve implantation. Other limitations are the small sample size drawn from a single hospital and the lack of measurement of the degree of annular overexpansion.

In conclusion, both MS length and left ventricular outflow tract calcification, assessed by multidetector computed tomography, are important predictors of the need for pacemaker implantation.

FUNDING

ETHICAL CONSIDERATIONS

As a a single-center retrospective observational study, without any kind of intervention, ethics committee approval was not deemed necessary, nor informed consents as anonymity was guaranteed. The decision to perform the tomography was taked at the doctor's discretion. According to the SAGER guidelines, sex and gender variables were taken into consideration.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence tools were used.

AUTHORS' CONTRIBUTIONS

D.I. Katekaru-Tokeshi conceived the study, conducted data collection and analysis, and drafted the manuscript. H.A. Ale-Gonzáles collected and analyzed data and contributed to manuscript drafting. P. Custodio-Sánchez analyzed the data and reviewed the manuscript. M. Jiménez-Santos interpreted the computed tomography studies and reviewed the manuscript. E. Kimura-Hayama reviewed both the manuscript and the images. F. Castillo-Castellón interpreted the computed tomography studies and critically revised the manuscript. All authors approved the manuscript final version.

CONFLICTS OF INTEREST

None.

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Comparison of long-term outcomes between a single versus a multiple stent brand strategy during *"full metal jacket"* procedures

Comparación de los resultados a largo plazo entre las estrategias de una y múltiples marcas de stent durante los procedimientos full metal jacket

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To the Editor,

Treatment failure is a major concern after full metal jacket (FMJ) stenting procedures, defined as overlapping stent length ≥ 60 mm. These procedures are often required to treat tandem or extensive coronary lesions.[1] Several brands of stents are currently approved, each displaying different characteristics and performance. However, real-world practice is not restricted to the use of a brand exclusive strategy and may involve a combination of different brands. Limited data exist on the relative safety and efficacy of these different strategies during percutaneous coronary intervention (PCI). Therefore, our aim was to compare clinical outcomes after the use of a single stent brand vs multiple stent brands following successful FMJ PCI.

From a dedicated database of 23 021 consecutive PCI procedures performed between January 2002 and December 2018 at a high-volume coronary intervention laboratory, we retrospectively identified 592 patients (3%) who underwent FMJ procedures. Written informed consent was obtained from all patients. Stent selection was left to the operator's discretion. We excluded patients with unsuccessful procedures and those lost to follow-up from the analysis. Demographic, clinical, angiographic, and procedural variables were evaluated. The primary endpoint consisted of major adverse cardiac events (MACE), which included all-cause death, myocardial infarction (MI), and target vessel revascularization (TVR). The secondary endpoint was target lesion failure (TLF), a composite of cardiac death, target vessel-related MI (TV-MI), and target lesion revascularization (TLR). Stent thrombosis and in-stent restenosis were also assessed. Clinical follow-up was conducted via telephone and hospital records were reviewed.

Univariate and multivariate Cox regression analysis were performed to determine independent predictors of outcome. All reported *P* values are 2-tailed, with a *P* value < .05 indicating statistical significance. Data were analyzed using IBM SPSS for Windows (version 25.0).

The study cohort included 353 patients, with a mean age 65.4 ± 11.4 years. Most of the patients were male (78%), presented with chronic stable angina (55%), and had a history of hypertension (77%) and

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Table 1. Long-term outcomes following full metal jacket procedure according to study groups

Events	All (n = 353)			Bare metal stents (n = 49)			First-generation DES (n = 35)			Second-generation DES (n = 107)			Third-generation DES (n = 162)		
	EBS group (n = 159)	MBS group (n = 194)	P value	EBS group (n = 18)	MBS group (n = 31)	P value	EBS group (n = 24)	MBS group (n = 11)	P value	EBS group (n = 32)	MBS group (n = 75)	P value	EBS group (n = 85)	MBS group (n = 77)	P value
	n (%)	n (%)		n (%)	n (%)		n (%)	n (%)		n (%)	n (%)		n (%)	n (%)	
MACE	63 (40)	98 (51)	.057	12 (67)	21 (68)	.945	14 (58)	6 (55)	.540	12 (38)	38 (51)	.049	25 (29)	33 (43)	.050
Death	34 (21)	56 (29)	.135	3 (17)	10 (32)	.288	7 (29)	4 (36)	.808	8 (25)	20 (27)	.685	16 (19)	22 (29)	.153
MI	22 (14)	34 (18)	.334	6 (33)	10 (32)	.969	6 (25)	1 (9)	.227	2 (6)	10 (13)	.179	8 (9)	13 (17)	.118
TVR	24 (15)	43 (22)	.075	5 (28)	8 (26)	.952	8 (33)	3 (27)	.577	4 (13)	21 (28)	.027	7 (8)	11 (14)	.184
TLF	38 (24)	76 (39)	.003	9 (50)	19 (61)	.573	7 (29)	6 (55)	.563	9 (28)	27 (36)	.211	13 (15)	24 (31)	.015
Cardiac death	11 (7)	27 (14)	.039	2 (11)	7 (23)	.339	2 (8)	1 (9)	.965	2 (6)	8 (11)	.477	5 (6)	11 (14)	.087
TV-MI	13 (8)	25 (13)	.151	3 (17)	7 (23)	.598	6 (25)	1 (9)	.227	1 (3)	9 (12)	.106	3 (4)	8 (10)	.083
TLR	23 (15)	38 (20)	.160	5 (28)	8 (26)	.952	7 (29)	3 (27)	.760	4 (13)	17 (23)	.076	7 (8)	10 (13)	.272
Stent thrombosis	8 (5)	7 (4)	.509	2 (11)	3 (10)	.897	6 (25)	1 (9)	.227	0 (0)	1 (1)	.695	0 (0)	2 (3)	.457
In-stent restenosis	23 (15)	53 (27)	.002	6 (33)	15 (48)	.271	2 (8)	6 (55)	.034	7 (22)	21 (28)	.205	8 (9)	11 (14)	.241

DES, drug-eluting stents; EBS, exclusive brand strategy; MACE, major adverse cardiac events; MBS, multiple brand strategy; MI, myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TV-MI, target vessel-related myocardial infarction; TVR, target vessel revascularization.

dyslipidemia (74%). A significant percentage of the patients had clinically overt cardiovascular disease (38%), including prior MI (24%), previous coronary revascularization with PCI (23%), or coronary artery bypass grafting (10%). Among the patients, 51 (14%) had left ventricular dysfunction (ejection fraction < 40%) and 63% had multivessel disease.

FMJ procedures were primarily performed via femoral access (71%) and targeted the right coronary artery in 57% of cases. The main indications were diffuse lesions (59%), followed by tandem lesions (23%) and dissection (10%). Ostial lesions, bifurcations, chronic total occlusions (CTO), and in-stent restenosis comprised 16%, 10%, 9%, and 7% of the procedures, respectively. Intracoronary imaging was used in 10% of the cases.

The mean number of stents was 2.95 ± 0.80 [range 2 to 6], the mean stent length was 74.3 ± 14.2 mm [range 60 to 132 mm], and the mean stent diameter was 2.88 ± 0.35 mm. Drug-eluting stents (DES) were used in 304 patients (86%), with contemporary third-generation DES accounting for 53% of the stents used. An exclusive brand strategy was employed in 45% of the procedures. In this group, the antiproliferative agents used were everolimus (56%), sirolimus (23%), zotarolimus (14%), umirolimus (5%), and paclitaxel (3%).

During the mean follow-up period of 5.0 ± 3.9 years, the incidence of MACE was 46% and the TLF rate was 32%. The all-cause mortality rate was 26%, of which 11% were cardiac deaths. The rates of MI and TV-MI were 16% and 11%, respectively. TVR occurred in 19% of the patients and TLR in 17%. The rates of stent thrombosis and in-stent restenosis were 4% and 22%, respectively.

Multivariate Cox analysis identified the use of a brand exclusive strategy as the only procedural-related protective factor for TLF (hazard ratio [HR], 0.552; 95% confidence interval [95%CI], 0.361-0.844; P = .006). When FMJ was performed using third-generation DES, over a mean follow-up of 3.1 ± 1.9 years, the occurrence rates of MACE and TLF were 36% and 23%, respectively. Similarly, after multivariate adjustment, the use of a single brand strategy

demonstrated a protective effect for TLF (HR, 0.444; 95%CI, 0.226-0.874; P = .019). There were no significant differences in procedural outcomes between distinct antiproliferative drugs or stent brands.

Clinical outcomes were then compared between the groups receiving a single stent brand and those receiving multiple stent brands (table 1). In the overall cohort, the use of a single stent brand resulted in a lower rate of MACE but this result was not statistically significant (HR, 0.735; 95%CI, 0.535-1.009; P = .057). However, the use of a single brand strategy demonstrated a protective effect against in-stent restenosis (HR, 0.458; 95%CI, 0.280-0.747; P = .002) and TLF (HR, 0.558; 95%CI, 0.378-0.824; P = .003). In FMJ using third-generation DES, brand exclusivity was found to be associated with a reduced incidence of TLF (HR, 0.432; 95%CI, 0.220-0.850; P = .015) and lower rate of MACE, although this result was not statistically significant (HR, 0.594; 95%CI, 0.353-1.000; P = .050).

A wide range of stents from various companies are currently available for clinical use, differing in their metal platform, polymer coating, and antiproliferative drug. While these stents generally have similar safety and efficacy, certain stents may perform better in some complex lesions, such as ostial, bifurcation, calcified, CTO, or long lesions that may require FMJ stenting.[2] Our study shows that FMJ PCI is associated with an acceptable, but nonnegligible, rate of events. The 1-year incidence of MACE was 15.6% (12.9% with the use of new-generation DES), which is in agreement with other published results.[3-5]

After multivariate adjustment, the use of a single brand strategy resulted in better outcomes in terms of in-stent restenosis and TLF. In addition, there was a trend toward lower MACE rates. Brand exclusivity remained a favorable strategy in the current-generation DES era. Of note, no particular stent brand demonstrated superiority over the others. Similarly, the eluted drug *per se* did not appear to play a significant role in determining clinical outcomes.

These findings suggest that procedural outcomes following successful FMJ procedures are not influenced solely by a specific

stent design or composition. Rather, they appear to be influenced by the combination of distinct stent profiles, differing in their physical, biological, and pharmacological properties, which may potentially lead to detrimental effects and influence outcomes.

This study provides novel results. However, several limitations must be acknowledged, mainly related to the retrospective, single-center and nonrandomized design. There was considerable loss to follow-up (37%), which may have led to bias. Therefore, these findings require validation in future dedicated trials.

In summary, our findings indicate that TLF is reduced by the use of a brand exclusive strategy in FMJ procedures, including in the era of third-generation DES. This suggests that avoiding a combination of different stent brands may be beneficial in this setting.

Informed consent was obtained from all participants involved in the study. The study was carried out in accordance with the principles of the Declaration of Helsinki and was approved by the local ethics committee.

FUNDING

ETHICAL CONSIDERATIONS

The study was carried out according to the principles of the Declaration of Helsinki and approved by the local ethics committee. Informed consent was obtained from all subjects involved in the study. The possible variables of sex and gender have been taken into account in accordance with the SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence was not used for the development of this work.

AUTHORS' CONTRIBUTIONS

J.M. Viegas was the major contributor in drafting the manuscript. The remaining authors revised the manuscript. All authors read and approved the final manuscript.

CONFLICTS OF INTEREST

None declared.

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"Tailored TAVI": the importance of the deployment mechanism

«Tailored TAVI»: la importancia del mecanismo de liberación

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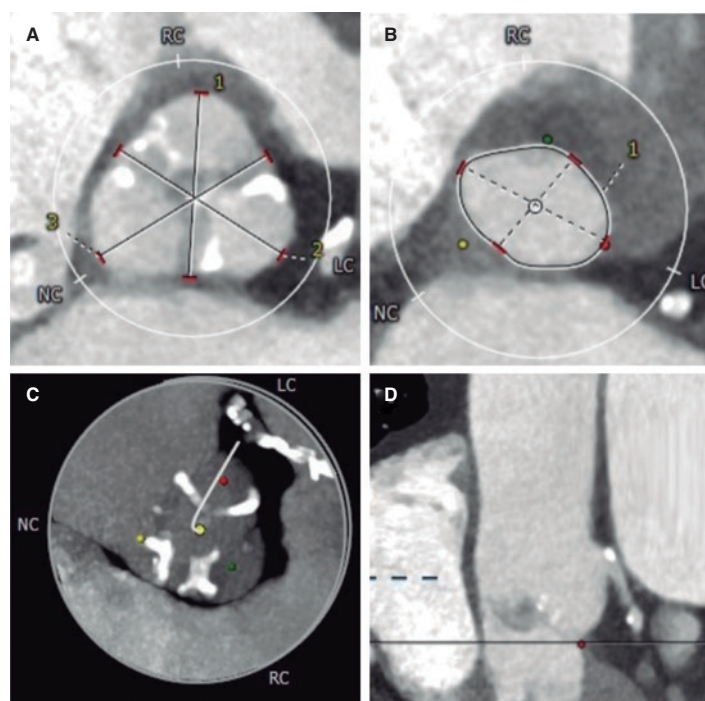
Figure 1.

A 78-year-old man with a past medical history of hypertension, pulmonary thromboembolism, atrial fibrillation, and prostate cancer presented with dyspnea. The patient was diagnosed with severe aortic stenosis (mean gradient, 49 mmHg; area of 0.7 cm^2), and severe ventricular hypertrophy. Heart function was preserved. The heart team decided to perform transcatheter aortic valve implantation (TAVI). Computed tomography revealed the presence of a scarcely calcified annulus with greater calcium distribution at the level of leaflet commissures and a 73.5-mm perimeter (figure 1).

We decided to implant a 23-mm self-expandable, supra-annular, fully recapturable, and nonrepositionable ALLEGRA valve (New-Valve-Technology, Switzerland). The valve was predilated using a 20-mm balloon but showed pop-up and distal migration towards the outflow tract despite pacing (figure 2A,B). The same complication occurred with a 27-mm ALLEGRA device. We then attempted to use a 29-mm CoreValve Evolut PRO+ valve (Medtronic, United States), because this device is fully repositionable, but the same complication recurred even with pacing (figure 2C,D).

Due to severe aortic regurgitation after the failed implantations, the patient became unstable (video 1 of the supplementary data). Considering the calcium distribution, we used the repositionable but not recapturable ACCURATE neo2 L valve (Boston Scientific, United States),

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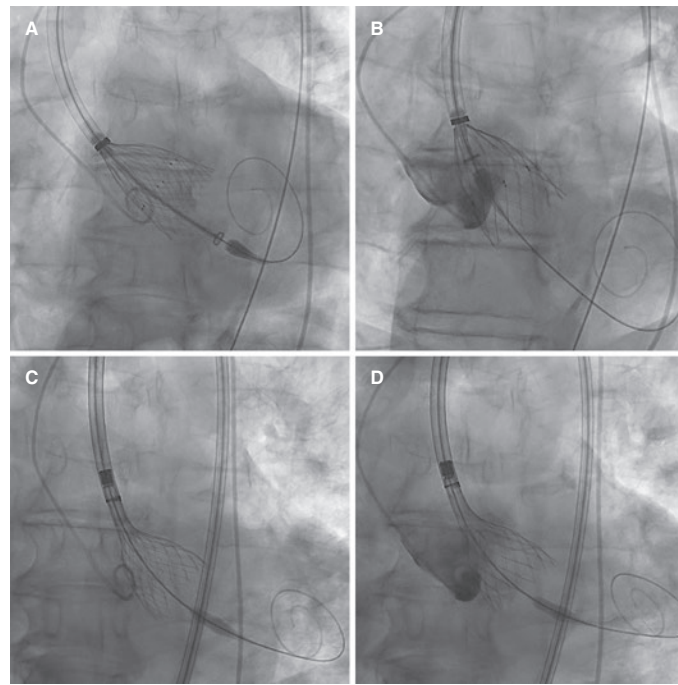
Figure 2.

which is equipped with stabilizing arches on the upper crown for the ascending aorta. The valve was then released and implanted under pacing, with an excellent final result. The patient's condition improved (video 1 of the supplementary data) and he was discharged uneventfully 5 days later, requiring a permanent pacemaker.

This case illustrates the advantages of familiarity with various valves and their distinct implantation mechanisms to achieve the necessary stability for a proper anatomical match. We believe that proficiency in assembling and using multiple valves is key to addressing technically challenging and clinically complex situations.

We obtained the patient's written informed consent for publication.

FUNDING

None.

ETHICAL CONSIDERATIONS

We obtained the patient's written informed consent for publication. As this is a unique case, the variables of sex and gender of SAGER guidelines do not apply.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No type of artificial intelligence or related technology was used in the writing of this article.

AUTHORS' CONTRIBUTIONS

S. López Tejero and P. Antúnez Muiños drafted the manuscript. A. Diego-Nieto and G. Barreira-de Sousa reviewed the medical literature available and revised the manuscript. I. Cruz-González and J. Martín-Moreiras conceived the study design, analyzed its topic specifically, revised the manuscript, and were its main supervisors.

CONFLICTS OF INTEREST

I. Cruz-González is a proctor for Medtronic, Boston-Scientific, and New Valve Technology. The remaining authors report no conflicts of interest.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE. M23000398.

Implantation of a pulmonary bioprosthetic valve in a single pulmonary artery

Implante de bioprótesis pulmonar en arteria pulmonar única

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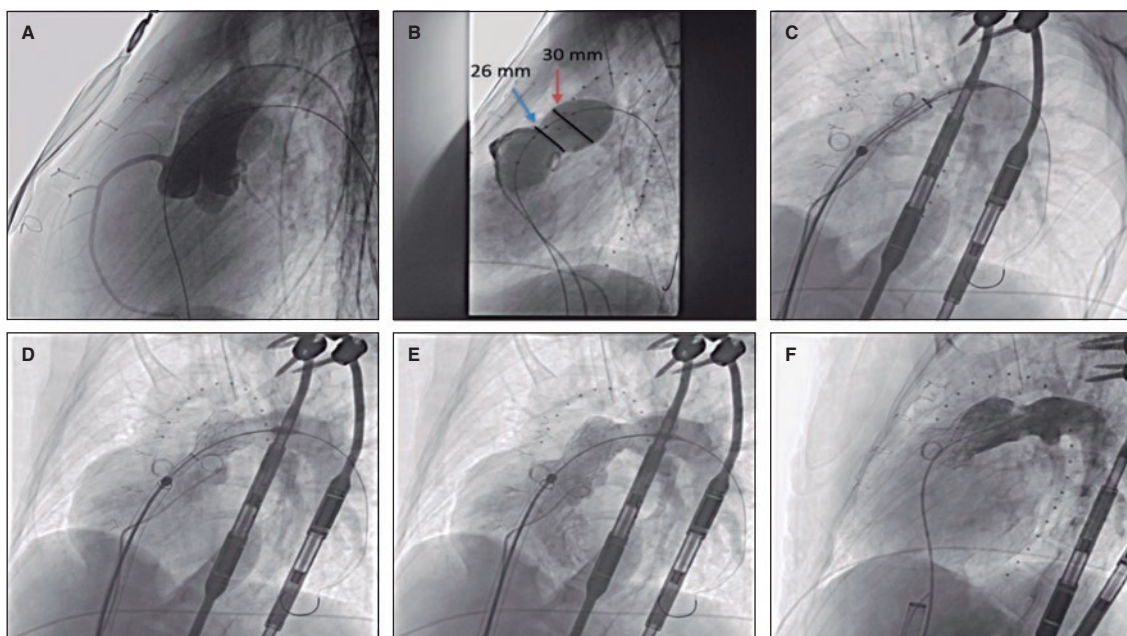
Figure 1.

We present the case of a 19-year-old woman with DiGeorge syndrome associated with psychomotor retardation, tetralogy of Fallot, and right pulmonary artery agenesis, treated with right ventricular outflow tract (RVOT) transannular patch augmentation during childhood, with severe pulmonary regurgitation and progressive right ventricular enlargement. As a result, pulmonary valve replacement was indicated. Cardiac computed tomography (CT) revealed the presence of severe scoliosis, right sternal deviation, and an elongated RVOT with a minimum diameter of 26 mm at the annular level and 30 mm at the supravalvular level (figure 1A-D, arrows). Because of the clinical and biomechanical characteristics, the anatomy of the RVOT, and the presence of a single pulmonary artery, we performed transcatheter implantation of a self-expanding bioprosthetic Venus valve (Medtech, China). Other valves suitable for large-caliber RVOTs, such as the Myval (Meril, India) have not been granted CE marking for pulmonary implantation.

Prior to implantation, the RVOT was sized, and coronary compression was ruled out after occlusive inflation with a 35-mm PTS-X sizing balloon catheter (NuMED, United States). The measurements obtained were consistent with the CT scan results. Consequently, a 30-mm to 25-mm valve was selected (figure 2A,B). A 24-Fr GORE DrySeal introducer sheath and an extra stiff Lunderquist wire guide (Cook Medical, United States) were used to access the left pulmonary artery and progressively deploy the valve initially from the distal segment at the origin of the pulmonary artery and subsequently the proximal segment. Withdrawal of the introducer sheath revealed optimal

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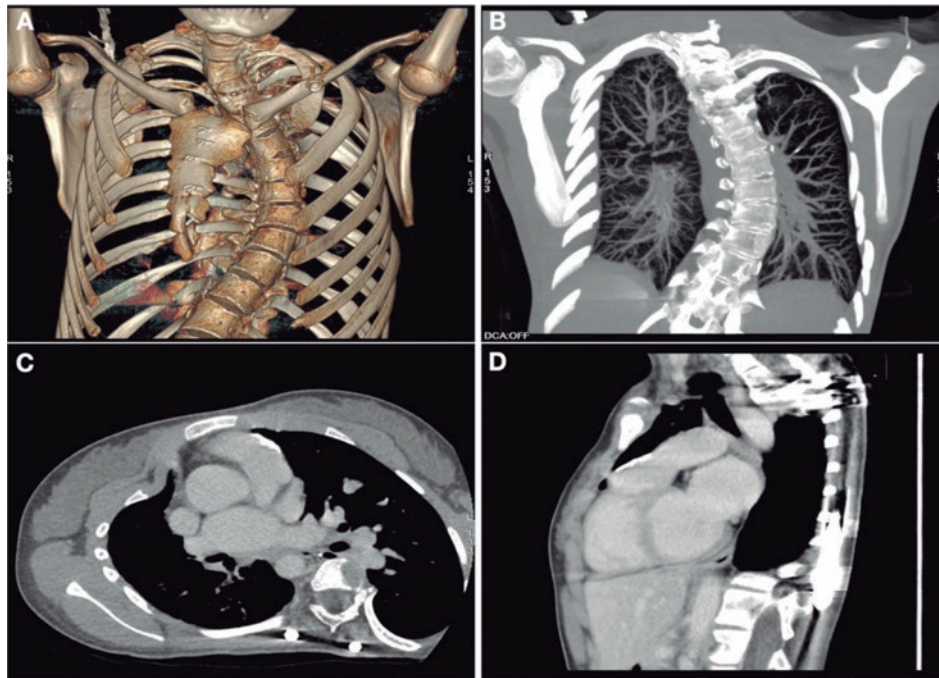*L. Fernández González et al. REC Interv Cardiol. 2024;6(1):57-58*

Figure 2.

apposition to the RVOT (figure 2C-F; videos 1 to 4 of the supplementary data). The patient was discharged from hospital 24 hours later, and the valve has remained fully functional ever since with no signs of residual valvular regurgitation.

The patient and her family gave their written informed consent for the publication of this article.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

The work has been approved by the ethics committee of our centre. Informed consent was obtained from the patient and family. Our work has not taken into account possible sex and gender variables in accordance with SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used.

AUTHORS' CONTRIBUTIONS

All the authors contributed equally to this work.

CONFLICTS OF INTEREST

None declared.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000407.

Transjugular left atrial appendage closure

Cierre percutáneo transyugular de orejuela auricular izquierda

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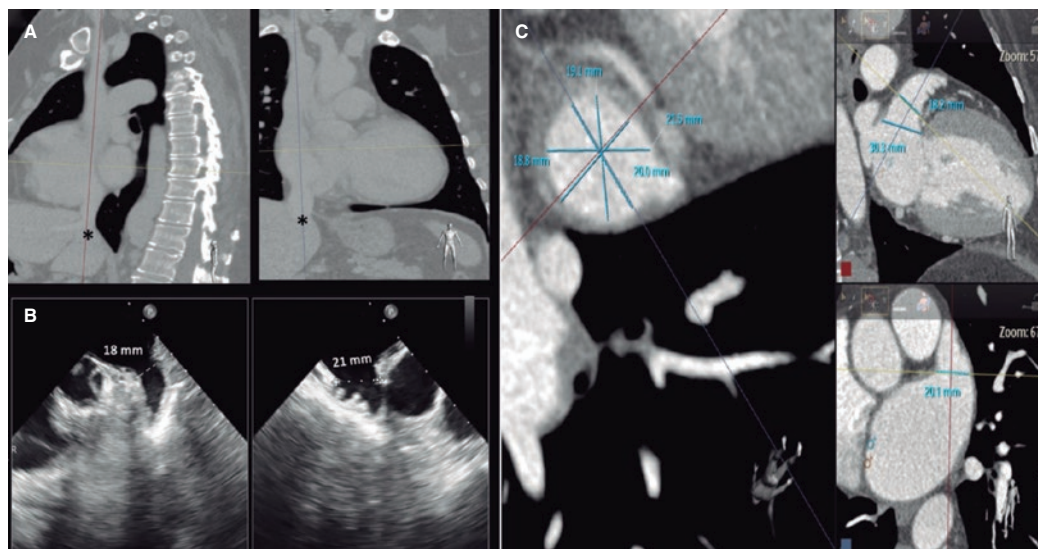[b] *Unidad de Imagen Cardiaca, Servicio de Cardiología, Complejo Hospitalario Universitario de Albacete, Albacete, Spain*

Figure 1.

A 52-year-old woman with atrial fibrillation, thrombocytopenia, and severe gastrointestinal bleeding while on several anticoagulants was referred for left atrial appendage closure. A year earlier, pulmonary vein ablation had been attempted but femoral access proved impossible due to a previously undetected congenital interruption of the inferior vena cava (figure 1A; asterisk). A right transjugular procedure was planned under general anesthesia and guided by transesophageal echocardiography and computed tomography-fluoroscopy fusion imaging (video 1 of the supplementary data). The left atrial appendage had a windsock morphology, with a mean diameter of 20 mm at the landing zone and 30 mm at the ostium (figure 1B,C). Consequently, a 24 mm x 30 mm LAmbre LAA Occluder system (LifeTech Scientific, China) was used, because its secure anchorage and closure mainly through the disk could facilitate the procedure. Transseptal puncture was performed using an SL1 sheath and a BRK-1 XS needle (Abbott, United States) by pre-shaping a secondary curve, followed by the insertion of a SafeSept guidewire (Pressure Products, United States) specifically designed for greater accuracy of transseptal puncture (figure 2A,B; the asterisk indicates the posterior and mid-puncture. Ao, aorta; LAA, left atrial appendage; SVC, superior vena cava). The device was implanted through a 10-Fr Fustar steerable sheath (LifeTech Scientific, China), which improved reach and coaxiality (figure 3A,B. E, extension; I, impulse; LOM, ligament of Marshall; MV, mitral valve; PR, posterior rotation). The patient was discharged at 24 hours without complications and on apixaban therapy (2.5 mg for 45 days).

Multimodal imaging, tools that facilitate precise transseptal puncture, and steerable sheaths can simplify the performance of procedures via upper access with efficiency and safety.

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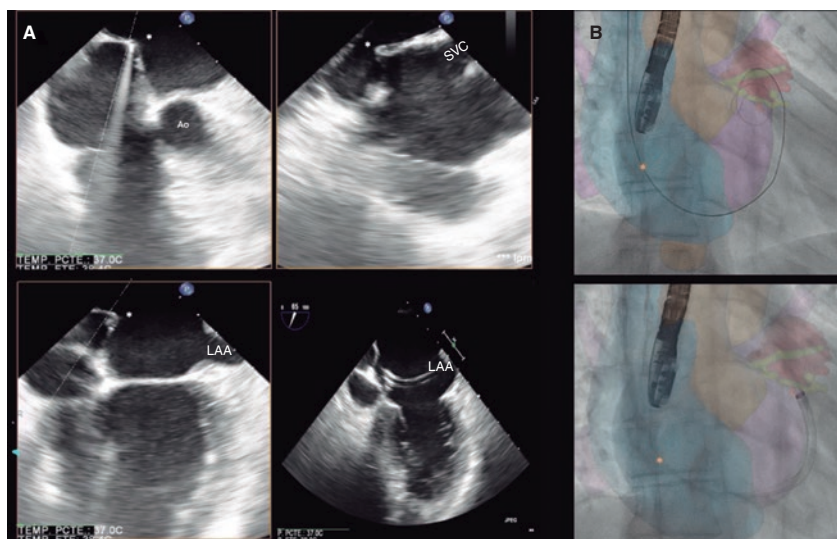*J.G. Córdoba-Soriano et al. REC Interv Cardiol. 2024;6(1):59-60*
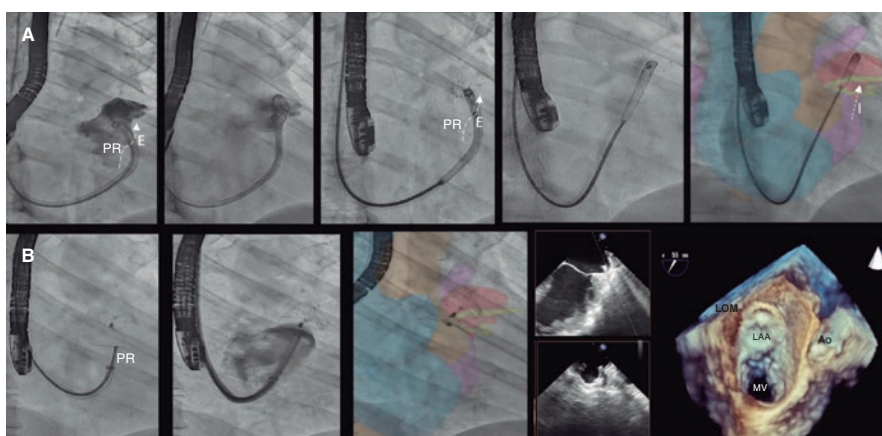
Figure 2.

Figure 3.

ETHICAL CONSIDERATIONS

This work was published after approval was obtained from the research ethics committee of *Complejo Hospitalario Universitario de Albacete*, Spain. The patient gave her prior written informed consent to the intervention and publication of her case. Sex and gender variables were taken into consideration based on the SAGER guidelines.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence tool has been used during the preparation of this work.

AUTHORS' CONTRIBUTIONS

All the authors participated in the drafting of this manuscript: J.G. Córdoba-Soriano was involved in drafting and design tasks, J.C. García-López in image selection and manuscript revision, and J. Jiménez-Mazuecos in manuscript revision and proofreading.

CONFLICTS OF INTEREST

None declared.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M23000410.